

Permissive weight bearing in trauma patients with peri- and intra-articular fractures of the lower extremities

Citation for published version (APA):

Kalmet, P. (2022). *Permissive weight bearing in trauma patients with peri- and intra-articular fractures of the lower extremities*. [Doctoral Thesis, Maastricht University]. Maastricht University. <https://doi.org/10.26481/dis.20221006pk>

Document status and date:

Published: 01/01/2022

DOI:

[10.26481/dis.20221006pk](https://doi.org/10.26481/dis.20221006pk)

Document Version:

Publisher's PDF, also known as Version of record

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

[Link to publication](#)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license above, please follow below link for the End User Agreement:

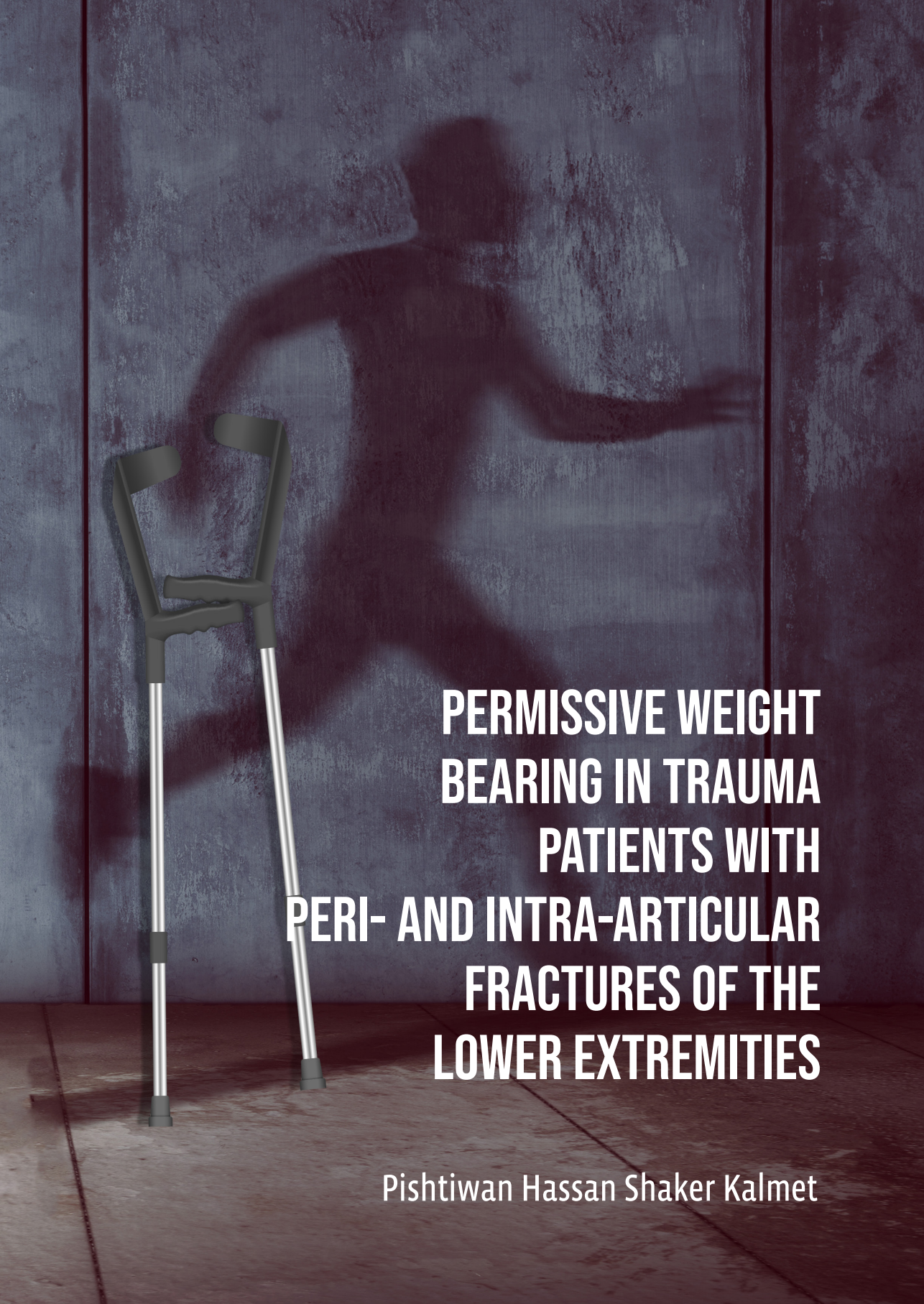
www.umlib.nl/taverne-license

Take down policy

If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

The background of the entire image is a dark, textured wall with vertical lines. In the lower-left foreground, a pair of black and silver crutches stands upright. Behind them, a large, dark shadow of a person in a running pose is cast onto the wall. The overall mood is one of urgency and recovery.

PERMISSIVE WEIGHT BEARING IN TRAUMA PATIENTS WITH PERI- AND INTRA-ARTICULAR FRACTURES OF THE LOWER EXTREMITIES

Pishtiwan Hassan Shaker Kalmet

Permissive weight bearing in trauma patients
with peri- and intra-articular fractures of the
lower extremities

Colofon

© Copyright Pishtiwan Kalmet, 2022

All rights reserved. No part of this book may be reproduced or transmitted in any form or by any means, without prior permission in writing by the author, or when appropriate, by the publishers of the publications.

Cover design: Ilse Modder, grafisch ontwerper

Layout: Tiny Wouters

Production: Gildeprint

ISBN: 978-94-6419-566-8

The work described in this thesis has received funding by the Netherlands Organization for Health Research and Development (ZonMW, project number 843001807). The insole material for this study was provided by the AO Foundation TK System (AOTK Project number: AO516.05).

The funders had no role in the design and conduct of the study; in the collection, management, analysis and interpretation of the data; in the preparation, review, or approval of the manuscript; or in the decision to submit the manuscript for publication.

Financial support by the Maastricht University for the publication of this thesis is gratefully acknowledged.

Permissive weight bearing in trauma patients with peri- and intra-articular fractures of the lower extremities

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,
op gezag van de Rector Magnificus, Prof. dr. Pamela Habibović,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen op
donderdag 6 oktober 2022 om 13.00 uur

door

Pishtiwan Hassan Shaker Kalmat
Geboren 25 december 1987 te Bagdad, Irak

Promotoren

Prof. dr. P.R.G. Brink

Prof. dr. M. Poeze

Copromotor

Dr. H.A.M. Seelen

Beoordelingscommissie

Prof. dr. J.A. Verbunt (voorzitter)

Prof. dr. M.J.R. Edwards, Radboud Universitair Medisch Centrum, Nijmegen

Prof. dr. J.H.B. Geertzen, Universitair Medisch Centrum, Groningen

Prof. dr. A.F. Lenssen

Dr. J.A. Ten Bosch

Table of contents

Chapter 1	Introduction: permissive weight bearing in lower extremity fractures	7
Chapter 2	Outline of thesis	17
Chapter 3	Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands	23
Chapter 4	The economic burden of the postoperative management in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities: a prospective multicenter cohort study	35
Chapter 5	A protocol for permissive weight bearing during allied health therapy in surgically treated fractures of the pelvis and the lower extremities: the first experience in 150 patients	49
Chapter 6	Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study	71
Chapter 7	Effectiveness of permissive weight bearing in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities: a prospective comparative multicenter cohort study	83
Chapter 8	Permissive weight bearing in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is cost-effective: a prospective comparative multicenter cohort study	101
Chapter 9	General discussion	121
	Summary	133
	Samenvatting	137
	Study impact	141
Appendix	Dankwoord	147
	List of publications	153
	Curriculum vitae auctoris	157



Chapter 1

Introduction:

Permissive weight bearing in lower extremity fractures

Meys G
Kalmet PHS
Poeze M
Seelen HAM

Acute Medical Rehabilitation. Text book volume 2. 2019

Accepted for publication

Introduction

A plethora of evidence is available about open reduction and internal fixation procedures in trauma patients with (peri)- or intra-articular fractures, as well as about the processes involved in bone healing.^{1,2} However, the subsequent rehabilitation treatment, or early aftercare, has been less systematically documented and is often based on empirical, implicit knowledge of individual medical or allied health therapists, acquired throughout many years of clinical practice. No formal evidence-based guidelines are available on the aftercare of surgically treated fractures. In view of this lack of evidence, many orthopaedic and trauma surgeons tend to advise conservatively with regard to weight bearing in rehabilitation, and hold on to the prevailing dogmas, i.e. recommending time-contingent progression of weight bearing, while physiotherapists and rehabilitation physicians may follow a more progressive approach towards fracture weight bearing. Besides, even with specific advice from specialists, patients may not always be committed to complying with non-weight bearing recommendations.^{3,4} It is remarkable that the recommendations for aftercare in patients surgically treated for fractures are still more or less the same as 60 years ago, without any sources of evidence being given for the advice.^{2,5} Furthermore, the lack of individual feedback on the actual weight bearing status causes great differences in weight bearing when the patient is advised restricted weight bearing.^{3,4,6} These circumstances give rise to a wide range of weight bearing patterns and inconsistent aftercare treatment.^{7,8}

Biomechanical and animal studies indicate that early weight bearing is beneficial.⁹⁻¹¹ Little is known about the relationship between fracture weight bearing during daily activities and the progression of consolidation of the fracture parts, the quality and function of the soft tissue, and biomechanical weight bearing capacity during the fracture healing. Fracture healing is an evolutionary well-developed complex process. One of the important factors influencing fracture healing is the amount of weight bearing of the involved limb. The speed with which the bone healing processes take place, together with the (aftercare) treatment provided, govern the progression with which weight bearing can be applied safely. Providing the adequate level of weight bearing on the fracture in a timely fashion during early aftercare treatment is considered essential in the speed towards full mobilisation.¹²⁻¹⁴

Both over-loading and under-loading may lead to a prolonged and complicated recovery (Figure 1.1). A certain minimum level of loading is necessary to elicit micro-movements between adjacent bony fracture components, stimulating biological processes that enhance fracture consolidation and minimizing effects of immobilization. The upper boundary of the therapeutic bandwidth is determined by the mechanical stability of the fracture and the stabilization method used. Under-loading

may lead to a host of problems such as loss of function, loss of muscle strength, loss of connective tissue's loading capacity, persistent edema, osteoporosis due to inactivity, and loss of joint mobility.^{15,16} Over-loading is considered to increase the frequency of failure of osteosynthesis with mal-union and non-union. To clinically optimize fast recovery and advance restoration of function and functionality, one may want to set out a treatment that is near to the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading. Also from a viewpoint of physiologic complexity and ageing, early recovery/rehabilitation is essential to ensure optimal outcome.^{17,18}

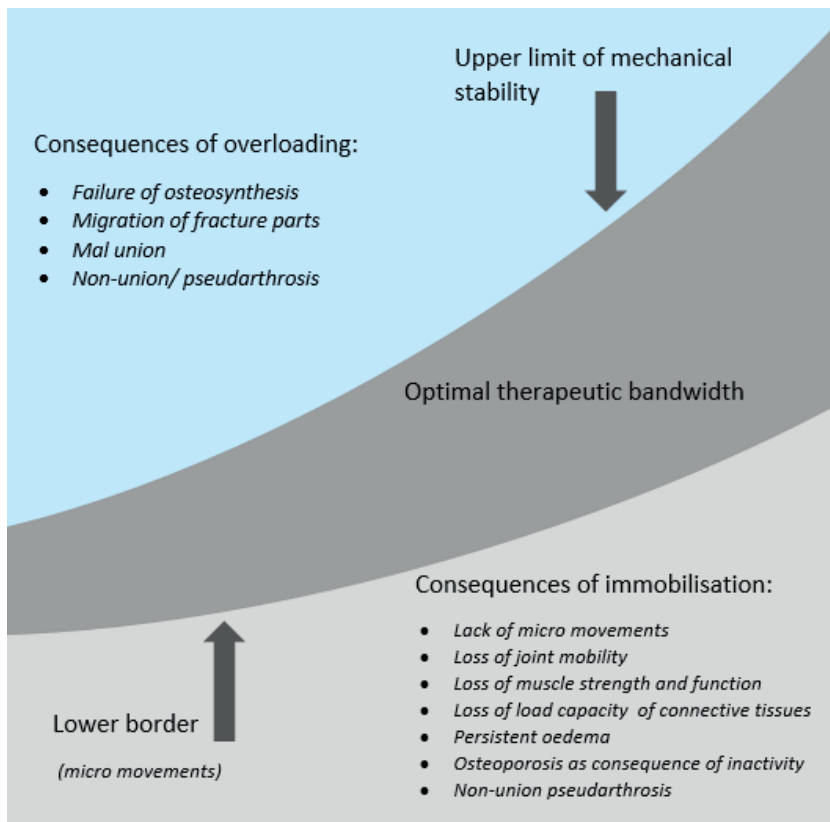


Figure 1.1 Schematic overview of the consequences of loading on the fracture consolidation process.

Clinicians prescribe non-weight bearing or partial weight bearing (restricted weight bearing (RWB) regimens) as standard treatment for peri-articular or intra-articular lower extremity fractures in an attempt to create an optimal protective mechanical environment at the different stages of healing. This strategy varies, based on the type of fracture, extent of the injury, and the preferences of the treating

surgeon.¹⁹ For peri- or intra-articular fractures, the recommended protocols include 6–12 weeks of non-weight bearing, after which a gradual increase to full weight bearing is recommended.² This restricted weight-bearing (RWB) strategy is thought to limit the forces at the fracture site and the implant and reduce the risk of mal-reduction. In light of the possible implications of early weight-bearing Haller et al. reviewed a number of studies investigating earlier weight bearing compared to standard, time-restraint weight bearing in tibial plateau, tibia plafond, ankle, and calcaneal fractures and found no increase in complication rate.²⁰ Especially a number of randomized controlled trials in ankle fractures provide compelling evidence for early weight bearing although the early weight bearing groups received additional plaster immobilisation for stabilization. As reported in a randomized controlled trial dealing with fractures of the ankle joint, early weight bearing does not pose an undue risk of complications or worse patient outcomes compared to a non-weight bearing protocol.²¹ Furthermore, a meta-analysis shows that following ankle surgery early weight-bearing tends to accelerate return to work and daily activities compared to late weight-bearing without higher risk of complications.²² Postoperative rehabilitation for tibial plateau fractures most commonly involves a significant period of non-weight bearing before full weight bearing is recommended at 8–12 weeks. A study by Solomon shows that, in tibial plateau fractures, internal fixation with subchondral screws and a buttress plate provided adequate stability to allow immediate post-operative partial weight-bearing, without harmful consequences.²³ Thus, the type of rehabilitation may be an important factor influencing recovery, necessitating future high quality prospective studies to determine the impact of different protocols on clinical and radiological outcomes.²⁴

The standard aftercare treatment in surgically treated trauma patients with fractures of the tibial plateau features is non- or partial weight bearing.² According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) principles of fracture management, postoperative management of (peri-) or intra-articular fractures of the lower extremities generally consists of toe-touch weight bearing for 6–12 weeks.² As to fractures caused by extremely high energy impact, patients may need to adhere to toe-touch weight bearing regimen for 10–12 weeks.² On the other hand, a survey about the adherence of current RWB protocols showed that almost 90% of the surgeons do not follow these protocols standardly regarding the weight bearing aftercare for tibial plateau fractures.¹⁹ In addition, there is currently no consensus among surgeons worldwide with regard to early weight bearing versus restricted weight bearing in surgically treated trauma patients with fractures of the tibial plateau.^{19,25} High-quality clinical studies about early or permissive weight bearing (PWB) are scarce.

Furthermore, to our knowledge there have been no studies on permissive weight bearing and its complications during rehabilitation from (peri-) or intra-articular fractures of the pelvis and lower extremities treated with internal fixation. Recent

literature has reported composite postoperative complication rates of up to 37% in non-weight bearing.²⁶⁻³⁵ To optimize recovery with a minimal complication rate, it might be useful to use a treatment that is near the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading, essentially the goals of the permissive weight bearing protocol.

Permissive weight bearing

Permissive weight bearing is a comprehensive protocol during rehabilitation and evaluation of surgically treated lower extremity fractures. This should enable a more systematic monitoring and guidance of the aftercare, based on patients' individual characteristics, characteristics of the surgically treated fractures, verifiable evidence-based criteria related to healing processes of surgically treated fractures, therapeutic milestones that may be set, indicators of progress that can be identified and evidence for the prevention of complications.

In an early aftercare treatment regimen for an individual patient with a surgically treated fracture of a lower extremity, rehabilitation specialists or therapists should address and/or systematically monitor several issues:

- a) Which realistic treatment outcomes may be aimed for, given the patient's specific fracture?
- b) How fast is the specific fracture consolidating in this patient?
- c) How fast does weight bearing capacity develop during bone healing, as this is essential in determining the pace at which training intensity may be safely increased?
- d) What kind of complications may be expected during the recovery process, which must be carefully monitored in order to take effective early counteractive measures?

Conclusion

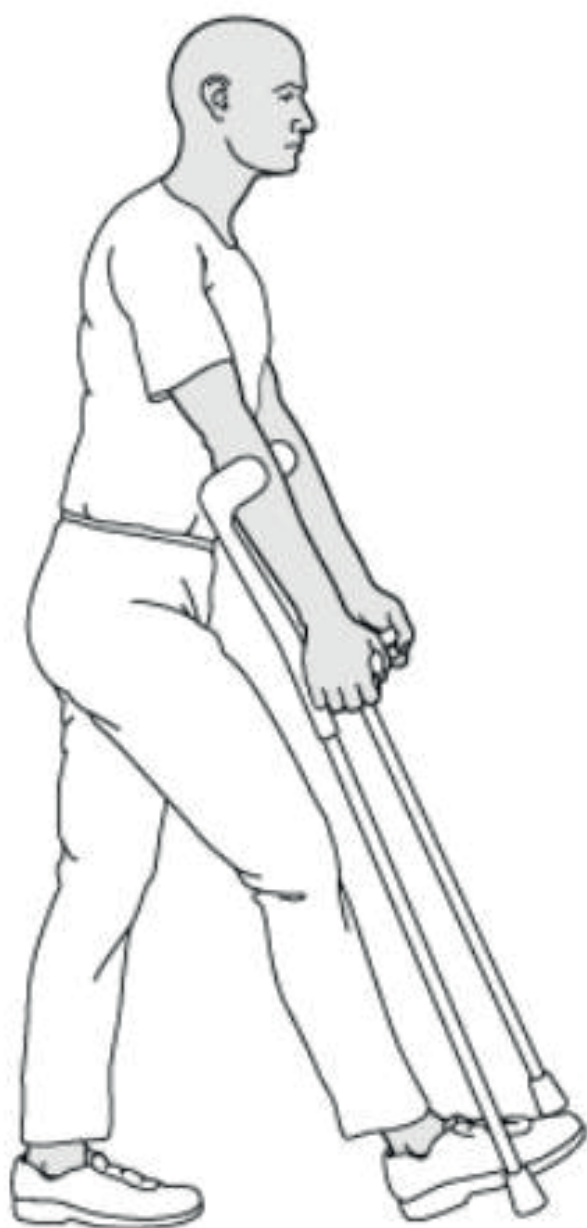
One of the main reasons for developing a systematic and comprehensive protocol has been the fact that, despite major improvements in surgical treatment and osteosynthesis materials, rehabilitation after surgical treatment of fractures has remained almost unchanged over the last six decades. The permissive weight bearing protocol has been developed in close cooperation between rehabilitation specialists, physical therapists and (orthopedic) trauma surgeons. It should serve as a general reference framework and a starting point for a discussion of the systematic optimization of the rehabilitation in patients with surgically treated fractures of the lower extremities, rather than as a library of predefined standard solutions

('cookbook'). To optimize recovery with a minimal complication rate, it is recommended to use a treatment that is near the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading, and that such treatment is guided by the permissive weight bearing protocol. Permissive weight bearing is a patient-tailored protocol. The protocol might be eligible for implementation in the treatment of trauma patients with surgically treated articular or (peri)- or intra-articular fractures of the pelvis and lower extremities.

References

1. AO_Foundation. Available from: <https://surgeryreference.aofoundation.org>. 2021.
2. Thomas P, Ruedi RE, Buckley CG, Moran. AO Principles of Fracture Management. Thieme, New York. 2007.
3. Gray FB, Gray C, McClanahan JW. Assessing the accuracy of partial weight-bearing instruction. *Am J Orthop* (Belle Mead NJ).1998;27:558-60.
4. Hurkmans HL, Bussmann JB, Selles RW et al. The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy: long-term vertical force measurements inside and outside the hospital. *Arch Phys Med Rehabil*. 2007;88:200-6.
5. Muller ME, Allgower M, Schneider R, Willenegger. *Manual of Internal Fixation Techniques*.Springer, Berlin. 1977.
6. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics*. 2012;35:e31-7.
7. Westby MD, Backman CL. Patient and health professional views on rehabilitation practices and outcomes following total hip and knee arthroplasty for osteoarthritis: a focus group study. *BMC Health Serv Res*. 2010;10:119-33.
8. Westby MD, Brittain A, Backman CL. Expert consensus on best practices for post-acute rehabilitation after total hip and knee arthroplasty: a Canada and United States Delphi study. *Arthritis Care Res*.2014;66:411-23.
9. Bailon-Plaza A, van der Meulen MC. Beneficial effects of moderate, early loading and adverse effects of delayed or excessive loading on bone healing. *J Biomech*. 2003;36:1069-77.
10. Claes LE, Heigele CA, Neidlinger-Wilke C et al. Effects of mechanical factors on the fracture healing process. *Clin Orthop Relat Res*. 1998:S132-47.
11. Gardner MJ, van der Meulen MC, Demetrakopoulos D et al. In vivo cyclic axial compression affects bone healing in the mouse tibia. *J Orthop Res*. 2006;24:1679-86.
12. Oldmeadow LB, Edwards ER, Kimmel LA et al. No rest for the wounded: early ambulation after hip surgery accelerates recovery. *ANZ J Surg*. 2006;76:607-11.
13. Augat P, Simon U, Liedert A, Claes L. Mechanics and mechano-biology of fracture healing in normal and osteoporotic bone. *Osteoporos Int*. 2005;16:S36-43.
14. Mavčič B, Antolič V. Optimal mechanical environment of the healing bone fracture/osteotomy. *Int Orthop*. 2012;36:689-95.
15. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. *Injury*. 2008;39:725-7.
16. de Morree JJ. Dynamics of human connective tissue [Dynamiek van het menselijk bindweefsel]. Houten, the Netherlands: Bohn Stafleu van Loghum. 2009.
17. Goldberger AL, Peng CK, Lipsitz LA. What is physiologic complexity and how does it change with aging and disease? *Neurobiol Aging*. 2002;23:23-6.
18. Manor B, Lipsitz LA. Physiologic complexity and aging: implications for physical function and rehabilitation. *Prog Neuropsychopharmacol Biol Psychiatry*. 2013;45:287-93.
19. van der Vusse M, Kalmet PHS, Bastiaenen CHG et al. Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands. *Arch Orthop Trauma Surg*. 2017;137:1071-5.
20. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture. What is the evidence? *Orthop Clin N Am*. 2013;44:509-19.
21. Swart E, Bezhan H, Greisberg J, Vosseller JT. How long should patients be kept non-weight bearing after ankle fracture fixation? A survey of OTA and AOFAS members. *Injury*. 2015;46:1127-30.
22. Smeeing DP, Houwert RM, Briet JP et al. Weight-bearing and mobilization in the postoperative care of ankle fractures: a systematic review and meta-analysis of randomized controlled trials and cohort studies. *PLoS One*. 2015;10:0118320.
23. Solomon LB, Callary SA, Stevenson AW et al. Weight-bearing-induced displacement and migration over time of fracture fragments following split depression fractures of the lateral tibial plateau: a case series with radiostereometric analysis. *J Bone Joint Surg Br*. 2011;93:817-23.

24. Arnold JB, Tu CG, Phan TM et al. Characteristics of postoperative weight bearing and management protocols for tibial plateau fractures: Findings from a scoping review. *Injury*. 2017;48:2634-42.
25. Kubiak EN, Beebe MJ, North K et al. Early weight bearing after lower extremity fractures in adults. *J Am Acad Orthop Surg*. 2013;21:727-38.
26. Choo KL, Morshed S. Postoperative complications after repair of tibial plateau fractures, *J Knee Surg*. 2014;27:11-9.
27. Koval KJ, Gilbert MS, Cornwall R. Functional outcomes and mortality vary among different types of hip fractures: a function of patient characteristics. *Clin Orthop Relat Res*. 2004;425:64-71.
28. Dong-Hyun LM, Keun-Bae L, Sung-Taek J. Comparison of Early Versus Delayed Weightbearing Outcomes After Microfracture for Small to Midsized Osteochondral Lesions of the Talus. *Am J Sports Med*. 2012;40:2023-8.
29. Hulsker CC, Kleinveld S, Zonnenberg CB et al. Evidence-based treatment of open ankle fractures. *Arch Orthop Trauma Surg*. 2011;131:1545-53.
30. Halvorson JJ, Winter SB, Teasdall RD et al. Talar Neck Fractures: A Systematic Review of the Literature. *J Foot Ankle Surg*. 2013;52:56-61.
31. Lasanianos NG, Lyras DN, Mouzopoulos G et al. Early mobilization after uncomplicated medial subtalar dislocation provides successful functional results. *J Orthop Traumatol*. 2011;12:37-43.
32. Mario Cala KB, Hany J. Early mobilization in bilateral talar fractures. *The Foot and Ankle Online J*. 2014;7:9.
33. Yu X, Pang QJ, Chen L et al. Postoperative complications after closed calcaneus fracture treated by open reduction and internal fixation: a review. *J Int Med Res*. 2014;42:17-25.
34. Schwabe P, Wichlas F, Druschel C et al. Komplikationen nach osteosynthetischer Versorgung von Azetabulumfrakturen [Complications after osteosynthetic treatment of acetabular fractures]. *Orthopäde*. 2014;43:24-34.
35. Papakostidis C, Kanakaris NK, Kontakis G et al. Pelvic ring disruptions: treatment modalities and analysis of outcomes. *Int Orthop*. 2009;33:329-38.



Chapter 2

Outline of thesis

This thesis describes the current state of practice among surgeons and cost-of-illness regarding non- or restricted weight bearing (RWB) (current guidelines), a comprehensive protocol for permissive weight bearing (PWB) and the (cost-) effectiveness of permissive weight bearing versus non- or restricted weight bearing.

The permissive weight bearing concept has been introduced in chapter 1, while the non- or restricted weight bearing protocol is the current guideline in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. However, as found in **chapter 1**, there are no studies done investigating the use of the permissive weight bearing protocol in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. The permissive weight bearing protocol might be beneficial and has potential to be implemented in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. Therefore, the purposes of the thesis were to describe the current state of practice among surgeons and the economic impact regarding non- or restricted weight bearing, a comprehensive protocol for permissive weight bearing and the (cost-) effectiveness of permissive weight bearing versus non- or restricted weight bearing. The hypothesis of this thesis is that the permissive weight bearing protocol in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities is more effective and cost-effective compared to the non- or restricted weight bearing protocol. Furthermore, the rate of complications (e.g. failure of osteosynthesis, secondary displacement of fracture parts, non-union, infections) is equal or lower in patients who are treated according to the permissive weight bearing protocol compared to patients treated according to the non- or restricted weight bearing protocol.

The following research objectives were formulated:

1. To investigate the current state of practice among orthopaedic surgeons and trauma surgeons in choosing the criteria and the time period of restricted weight bearing after surgically treated tibial plateau fractures.
2. To determine the economic impact of the (after)care in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities
3. To describe a comprehensive protocol for permissive weight bearing during allied health therapy and to report on both the time to full weight bearing and the number of complications in patients with surgically treated fractures of the pelvis and lower extremities who undergo permissive weight bearing.
4. To compare quality of life and pain, and number of complications in patients with surgically treated tibial plateau fractures who followed a permissive weight bearing regime, relative to those that followed a restricted weight bearing regime.
5. To determine the effectiveness of the permissive weight bearing protocol compared with respect to early recovery (during first 6 months) of functional

outcome in trauma patients with peri- and intra-articular fractures of the lower extremities, compared to a non- or restricted weight bearing protocol.

6. To compare the cost-effectiveness and the cost-utility of the permissive weight bearing protocol to that of the non- or restricted weight bearing protocol, being care as usual.

These six research objectives were addressed in the subsequent chapters of this thesis.

As described in the introduction, rapid clinical recovery, the restoration of function and functionality and low complication rates are considered the most important conditions for using an early or permissive weight bearing protocol in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities. In **chapter 3** of this thesis, the objective was to investigate the current state of practice among orthopaedic surgeons and trauma surgeons in choosing the criteria and the time period until weight bearing after surgically treated tibial plateau fractures. A web-based survey was distributed among members of the Dutch Trauma Society and Dutch Orthopaedic Society to identify the most commonly applied protocols in terms of the post-operative initiation and level of weight bearing in patients with tibial plateau fractures.

The aim of the study in **chapter 4** was to determine the economic impact of the (after)care of peri- and intra-articular fractures in the lower extremity, based on a prospective prevalence-based cohort study from health care and societal perspective. Surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities following a non- or restricted weight bearing protocol were included. This study was an economic burden study focusing on costs (in euros), Activities of Daily Living (ADL) as measured with the Lower Extremity Functional Scale (LEFS) and the Quality of Life (QoL) as measured with the EuroQol 5-Level EQ-5D (EuroQol) during 26 weeks follow-up.

In **chapter 5**, the aim of the study was to describe a comprehensive protocol for permissive weight bearing during allied health therapy and to report on the time to full weight bearing as well as the number of complications in patients with surgically treated fractures of the pelvis and lower extremities undergoing permissive weight bearing. This study included surgically treated trauma patients with (peri)- and/or intra-articular fractures of the pelvis and lower extremities. A standardized permissive weight bearing protocol was used for all patients. Time to full weight bearing and number of complications were recorded.

In a retrospective cohort study (**chapter 6**) the aim was to inventory potential differences in quality of life and pain, and number of complications in patients with

surgically treated tibial plateau fractures who followed a permissive weight bearing regime, relative to those that followed a restricted weight bearing regime. This study included surgically treated trauma patients with tibial plateau fractures, who underwent rehabilitation according to permissive weight bearing or restricted weight bearing between 2005-2015.

In **chapter 7 and 8**, the effectiveness (**chapter 7**) and cost-effectiveness (**chapter 8**) of the permissive weight bearing protocol in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities were compared to those that followed a non- or restricted weight bearing protocol. This prospective multicenter comparative cohort study included surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities using permissive weight bearing and restricted weight bearing groups regimens.



Chapter 3

Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands

van der Vusse M
Kalmet PHS
Bastiaenen CHG
van Horn YY
Brink PRG
Seelen HAM

Arch Orthop Trauma Surg. 2017;137(8):1071-1075

Abstract

Introduction

The standard aftercare treatment (according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) guideline) for surgically treated trauma patients with fractures of the tibial plateau is non-weight bearing or partial weight bearing for 10-12 weeks. The purpose of this study was to investigate the current state of practice among orthopaedic surgeons and trauma surgeons in choosing the criteria and the time period of restricted weight bearing after surgically treated tibial plateau fractures.

Materials and methods

A web-based survey was distributed among members of the Dutch Trauma Society and Dutch Orthopaedic Society to identify the most commonly applied protocols in terms of the post-operative initiation and level of weight bearing in patients with tibial plateau fractures.

Results

One hundred and eleven surgeons responded to the survey. 72.1% of the respondents recommended starting weight bearing earlier than the 12 weeks recommended by the AO guideline; 11.7% recommended starting weight bearing immediately, 4.5% after 2 weeks and 55.9% after 6 weeks. Moreover, 88.7% of the respondents reported deviating from their own local protocol. There is little consensus about the definition of 100% weight bearing and how to build up weight bearing over time.

Conclusion

This study demonstrates that consensus about the weight bearing aftercare for tibial plateau fractures is limited. A large majority of surgeons do not follow the AO guideline or their own local protocol. More transparent criteria and predictors are needed to design optimal weight-bearing regimes for the aftercare of tibial plateau fractures.

Introduction

The incidence of tibial plateau fractures is approximately 13.3 per 100,000 persons.¹ The postoperative management of these surgically treated fractures in trauma patients is of the utmost importance for a full recovery of knee function and the patient's participation in daily activities and work. Tibial plateau fractures are a cause of long-term disability and pain, and frequently lead to many weeks off work, with substantial economic effects.

The standard aftercare treatment in surgically treated trauma patients with fractures of the tibial plateau is non-weight bearing or partial weight bearing.² According to the AO Principles of Fracture Management, postoperative management of tibial plateau fractures consists of generally maintained on toe-touch weight bearing for 6–8 weeks. Exceptions are fractures caused by extremely high energy; these patients might need to adhere to toe-touch weight bearing for 10–12 weeks.³ However, there is currently no worldwide consensus among surgeons with regard to permissive weight bearing versus restricted weight bearing in surgical trauma patients with fractures of the tibial plateau.⁴ Permissive weight bearing might be early weight bearing, but this not the goal as such. In permissive weight bearing the patient dictates the progress in weight bearing together with the physiotherapist.

Although biomechanical and animal studies suggest that early weight bearing is beneficial,^{5–7} there have been virtually no high-quality clinical studies comparing permissive weight bearing (PWB) with restricted weight bearing (RWB) after surgically treated tibial plateau fractures.

The purpose of the present survey was to investigate the current state of postoperative practice among Dutch orthopaedic surgeons and trauma surgeons regarding patients with surgically treated tibial plateau fractures. The survey asked whether they adhered to the AO guideline and their own local guidelines and which criteria they used to decide when and at what level to start weight bearing after surgery.

Materials and methods

A web-based survey was developed by the authors and was distributed among Dutch orthopaedic surgeons and trauma surgeons, using online software (www.formdesk.nl). The survey was publicised at the Dutch trauma congress in 2013 and placed on the websites of the Dutch Trauma Society and the Dutch Orthopaedic Society. Together,

the two societies comprise 1293 members. In addition, we approached the surgeons through direct email at their hospital departments in the period of November 2013 – October 2014. The survey consisted of twelve questions, shown in Table 1.1.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics, Version 21.0, Armonk, NY. Descriptive statistics were used to describe the demographic data and baseline characteristics of the entire survey. Results are presented as either mean \pm standard deviation (SD) or as frequencies and percentages.

Table 3.1 The questionnaire.

1)	What is your discipline?
2)	How long have you been a surgeon?
3)	How often do you operate a tibial plateau fracture on yearly basis?
4)	When do you start aftercare weight bearing in patients with tibial plateau fractures and with which weight bearing percentage?
5)	Do you occasionally deviate from the standard postoperative protocol used in your clinic?
6)	If you deviate from the standard protocol, on which factors is your decision based?
7)	Which criteria do you use to determine earlier or delayed weight bearing?
8)	How do you define 100% weight bearing?
9)	How do you (gradually) increase postoperative weight bearing?
10)	What kind of early complications do you see in patients with tibial plateau fractures in your clinic?
11)	Are these complications related to early weight bearing?
12)	Do you see yourself as a surgeon who is a more conservative or more progressive in the aftercare of tibial plateau fractures?

Results

Of the 111 surgeons who responded in the survey, 61 (55.0%) were orthopaedic surgeons and 50 (45.0%) were trauma surgeons. The overall response rate was 8.6% (i.e. 111/1293). Thirty-eight (34.2%) of the respondents were for 0-5 years surgeon, N=21 (19.0%) 5-15 years and N=52 (46.8%) more than 15 years surgeon. On yearly basis, N=44 (39.6%) operated less than 5 times a tibial plateau fracture, N=51 (46.0%) between 5-10 times and N=16 (14.4%) more than 10 times per year.

Surgeons were asked when they started weight bearing after surgical treatment of tibial plateau fractures and with which weight bearing percentage. The results are shown in Figure 3.1: 11.7% of the respondents started immediately with weight bearing, 4.5% after 2 weeks, while the majority (55.9%) recommended starting weight bearing 6 weeks post-operatively. Only 15.3% recommended weight bearing after 12 weeks, i.e. in line with the AO guideline. Furthermore, 12.6% of the respondents

recommended that the start of weight bearing should depend on the type of fracture and the osteosynthesis material. These findings imply that 72.1% of the respondents recommended starting weight bearing earlier than the 12-week period recommended by the AO guideline.

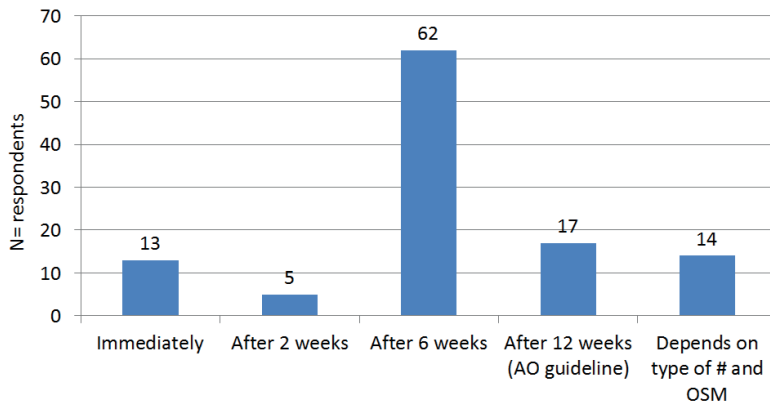


Figure 3.1 When do you start weight bearing after tibial plateau fractures and with what weight bearing percentage?

Figure 3.2 shows that 88.7% of the respondents occasionally deviated from their local standard protocol, in most cases based on clinical experience (38.7%) and gut feeling (35.1%), while 19.8% of the respondents deviated on the basis of so-called evidence-based medicine, even though the latter is scarce in the literature.

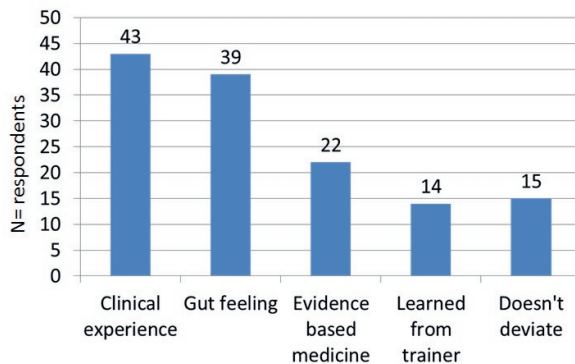


Figure 3.2 Reasons for deviating from own standard local protocol.

Frequently mentioned reasons for starting weight bearing earlier or later were fracture type [N=87 (78.4%) and N=83 (74.8%), respectively], certainty or uncertainty of fixation quality [N=66 (59.5%) and N=74 (66.7%), respectively], age [N=46 (41.4%) and N=38 (34.2%), respectively] and additional traumata [N=0 (0.0%) and N=50 (45%), respectively]. The two most important influencing aspects to bear weight earlier or later is the type of fracture and the certainty or uncertainty of fixation, (Figure 3.3).

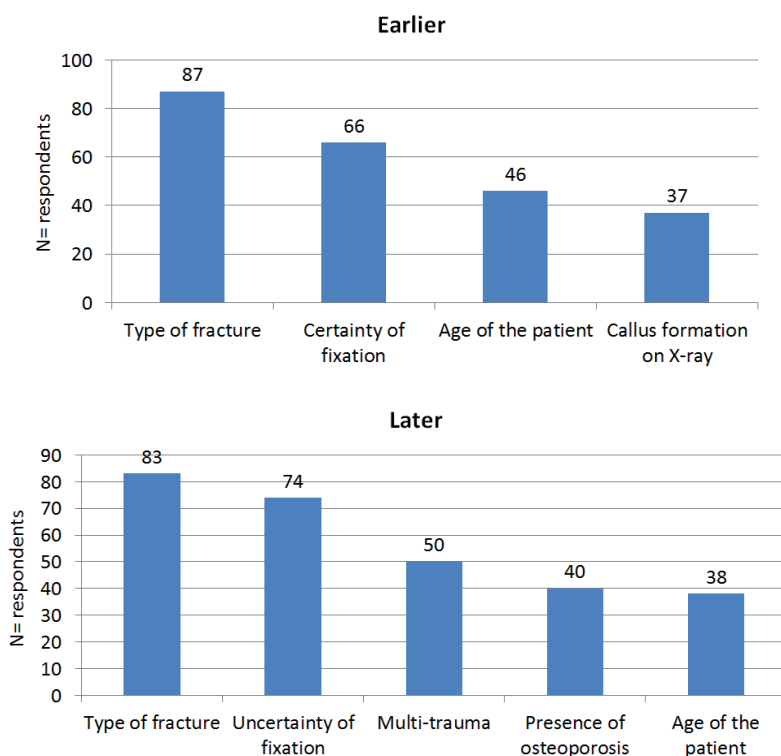


Figure 3.3 Which criteria are used to decide earlier or later weight bearing?

Surgeons who recommended starting weight bearing immediately or after 2 weeks mostly commenced with a low dosage (10%-25%) of weight bearing (Table 3.2). If weight bearing started 6 weeks post-operatively, this was mainly at 50% (27 respondents) or 10%-25% (21 respondents) of the maximum level. When patients started weight bearing 12 weeks after the surgical treatment, 10 out of 11 surgeons recommended starting immediately with 100% weight bearing. Since it is important to know what surgeons regard as “100% weight bearing”, we asked for their definition of “100% weight bearing”, results of which are shown in Figure 3.4. The majority, i.e. 45 (40.5%) respondents, defined this as “walking without crutches”, 35 (31.5%)

respondents indicated “standing on one leg of the affected side”, 20 (18.0%) respondents mentioned “walking with crutches” and 10 (9.0%) respondents considered “100% weight bearing” to be “running, jumping, climbing a staircase”.

Table 3.2 Level of weight bearing (percentage) patients are allowed to start with.

Maximal weight bearing (%)	Direct/Early weight bearing	After 2 weeks	After 6 weeks	After 12 week (AO-guideline)	Depends on type # and OSM
10-25%	10	4	21	0	0
50%	1	0	27	1	0
75%	0	0	1	0	0
100%					
Weight bearing without %	1	0	7	6	14
Total	13	5	62	17	14

= fracture; OSM = osteosynthesis material

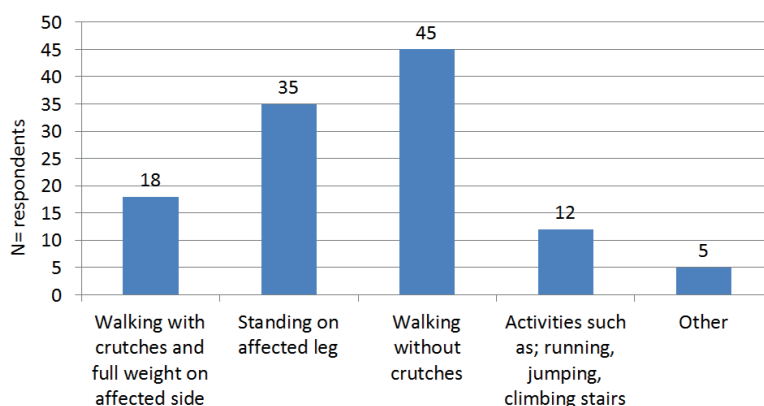


Figure 3.4 Definition of “100% weight-bearing” used by surgeons.

Most surgeons (N=48, 43.2%) told their patients that weight bearing should increase gradually over a fixed number of weeks, expressed in kilograms or percentage of body weight. Twenty-nine (26.0%) surgeons recommended gradually increasing weight over a fixed number of weeks to a level of 100%, based on how much weight bearing the patient could tolerate. Twenty-nine (26.0%) surgeons recommended permissive weight bearing, which means surgeons let patients and therapists decide how to build up the weight bearing as tolerated (Figure 3.5). Of the 29 (26.0%) respondents who recommended permissive weight bearing, N=12 (10.8%) were orthopaedics and N=17 (15.3%) were trauma surgeons. Eight (7.2%) respondents who recommended permissive weight bearing had a work experience of 0-5 years, N=14 (12.6%) 5-15 years and N=7 (6.3%) more than 15 years. In this group N=9 (8.1%)

operated less than 5 times, N=16 (14.4%) between 5-10 times and N=4 (3.6%) more than 10 times. Fifty-three (47.7%) of the respondents were conservative in the aftercare of tibial plateau fractures and N=58 (52.3%) were progressive in the aftercare.

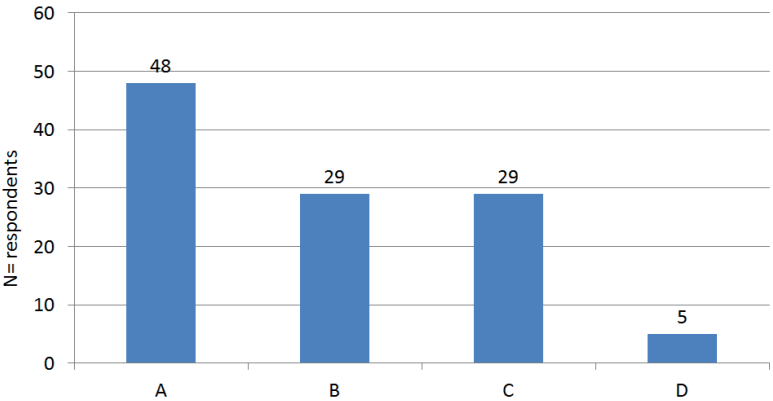


Figure 3.5 How do surgeons advise their patients about increasing weight bearing following a graded protocol?
A: Graded increase over time in a fixed number of weeks, expressed in kilogram or percentage of body weight
B: Graded increase over a fixed number of weeks, expressed as as much weight bearing as tolerated by the patient
C: Permissive weight bearing, which means surgeons let patients and therapists decide how to build up the weight bearing as tolerated
D: Other.

Discussion

This survey is an attempt to obtain up-to-date information on the time period between surgical treatment of tibial plateau fractures and the start of rehabilitation involving weight bearing. The AO guideline for postoperative management of tibial plateau fractures was formulated about 50 years ago and suggests restricted weight bearing for approximately 12 weeks.³ It is generally assumed that orthopaedic surgeons and trauma surgeons follow the AO guideline, advocating restricted weight bearing during aftercare for the patients. Interestingly, the present study shows that a large proportion of orthopaedic surgeons and trauma surgeons in the Netherlands recommended starting weight bearing earlier than 12 weeks. In practice, the vast majority of the responding surgeons deviated from their own institutional guidelines, based on clinical experience and gut feeling, thus deviating from the AO guideline.

The period of delayed weight bearing was reported to depend, *inter alia*, on the fracture type, certainty or uncertainty about fixation quality and additional traumata. To date, we have not been able to identify studies providing methodologically sound evidence as to critical factors that may assist in the decision to start weight bearing earlier or later. However, many studies have shown a trend towards favouring earlier weight bearing. Longer-term outcomes have also been described in the literature, with no negative effects of early weight bearing being reported.⁸⁻¹³

It is important to note that this study did not intend to determine the optimal aftercare for a given tibial plateau fracture, but was designed to disclose the current practice regarding tibial plateau fracture surgery aftercare and the factors on which orthopaedic surgeons and trauma surgeons found their decisions.

This study clearly demonstrates that there is as yet no consensus about the aftercare of tibial plateau fractures. Furthermore, there is no evidence to restrict patients in bearing weight for 10-12 weeks as suggested by the AO guideline. Our findings show that at least in the Netherlands, the AO guideline is not decisive. In addition, we found large variations in post-operative rehabilitation treatment.

It should be kept in mind that another complicating factor could be lack of patient compliance with prescribed rehabilitation aftercare.^{14,15} A number of studies reported that patients often exceeded the prescribed level of partial weight bearing, even when self-reported compliance was high.¹⁶ Thus, despite the expressed willingness to comply, patients often do not follow the restrictions on weight bearing and increase their weight bearing as fracture healing progresses. Together with the finding that there is no consensus as to what the definition of “100% weight bearing” is and how to build up weight in a protocolled way, our study revealed a large diversity in practical weight bearing usage among surgeons. This makes it even more difficult to achieve a good interpretation of the aftercare and offer customized advice to patients regarding the optimal aftercare in terms of weight bearing during the rehabilitation.

There are a few important limitations of this study. The study is limited by the response rate. The survey didn't describe the different types of fractures and assumptions regarding the energy of trauma. Furthermore, it is important to note that this study does not attempt to describe what the correct aftercare treatment is in tibial plateau fractures, but rather to obtain up-to-date information on the time period between surgical treatment of tibial plateau fractures and the start of rehabilitation involving weight bearing. In summary, the outcome of this survey shows that there is no clear consensus about optimal postoperative treatment of patients with a tibial plateau fracture, which may result in suboptimal rehabilitation aftercare. This leaves open the question what is the optimal rehabilitation treatment in surgically treated

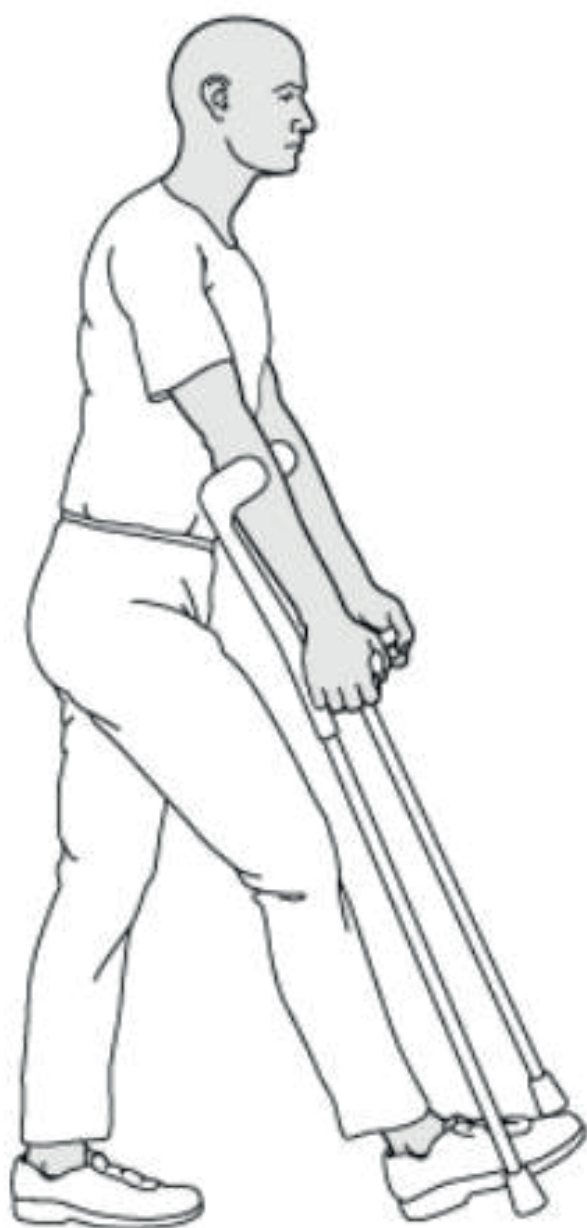
tibial plateau fractures. To answer this question, the authors recommend that both the AO guideline and current local institutional guidelines should be critically scrutinized to establish the optimal aftercare for these patients. In theory, it is normally the surgeon who decides which aftercare protocol should be followed. Most often, this is a restricted weight-bearing regime with a build-up time over a fixed number of weeks. In practice, such protocols are not followed very strictly. As 26% of the respondents would like to advocate using a customized permissive weight bearing protocol, as well as studies by Solomon et al and Segal et al which support individualized permissive weight bearing.^{13,17} However, high-quality prospective studies are needed to help identify which criteria and predictive factors are important for developing a (permissive) weight bearing protocol to optimize patients' comfort and optimize the course of recuperation.

Conclusion

This study demonstrates that consensus about the weight bearing aftercare for tibial plateau fractures is limited. A large majority of surgeons do not follow the AO guideline or their own local protocol. More transparent criteria and predictors are needed to design optimal weight-bearing regimes for the aftercare of tibial plateau fractures.

References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. *Injury*. 2006;37(8):6917.
2. Haller JM, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthopedic Clinics of North America*. 2013; 44(4):509–19.
3. Rüedi TP, Buckley RE, Moran CG. *AO Principles of Fracture Management*. 2007; 2nd edition (New York: Thieme): 832.
4. Kubiak EN, Beebe MJ, North K et al. Early weight bearing after lower extremity fractures in adults. *J Am Acad Orthop Surg*. 2013;21(12):727–38.
5. Bailon-Plaza A, van der Meulen MC. Beneficial effects of moderate, early loading and adverse effects of delayed or excessive loading on bone healing. *J Biomech*. 2003;36(8):1069–77.
6. Claes LE, Heigele CA, Neidlinger-Wilke C et al. Effects of mechanical factors on the fracture healing process. *Clin Orthop Relat Res*. 1998;S132–47.
7. Gardner MJ, van der Meulen MC, Demetrakopoulos D et al. In vivo cyclic axial compression affects bone healing in the mouse tibia. *J Orthop Res*. 2006;24(8):1679–86.
8. Kutzner I, Heinlein B, Graichen F et al. Loading of the knee joint during activities of daily living measured in vivo in five subjects. *J Biomech*. 2010;43(11):2164–73.
9. Brown TD, Anderson DD, Nepola JV et al. Contact stress aberrations following imprecise reduction of simple tibial plateau fractures. *J Orthop Res*. 1988;6:851–62.
10. Solomon LB, Callary SA, Stevenson AW et al. Weight-bearing-induced displacement and migration over time of fracture fragments following split depression fractures of the lateral tibial plateau: a case series with radiostereometric analysis. *J Bone Joint Surg Br*. 2011;93(6):817–23.
11. Canadian Orthopaedic Trauma S. Open reduction and internal fixation compared with circular fixator application for bicondylar tibial plateau fractures. Results of a multicenter, prospective, randomized clinical trial. *J Bone Joint Surg Am*. 2006;88(12):2613–23.
12. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. *Injury*. 2008;39(7):725–7.
13. de Morree JJ. *Dynamics of human connective tissue*. 2009, Houten, the Netherlands: Bohn Stafleu van Loghum.
14. Hurkmans HL, Bussmann JB, Selles RW et al. The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy: Long-term vertical force measurements inside and outside the hospital. *Arch Phys Med Rehabil*. 2007;88: 200–6.
15. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics*. 2012;35: e31–e37.
16. Warren CG, Lehmann JF. Training procedures and biofeedback methods to achieve controlled partial weight bearing: an assessment. *Arch Phys Med Rehabil*. 1975;56(10):449–55.
17. Segal D, Mallik AR, Wetzler MJ et al. Early weight bearing of lateral tibial plateau fractures. *Clin Orthop Relat Res*. 1993;(294):232–7.



Chapter 4

The economic burden of the postoperative management in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities: a prospective multicenter cohort study

Kalmet PHS
Andriessen MT
Maduro CV
van den Boom NAC
Moens-Oyen CPA
Hiligsmann MJC
Janzing H
van der Veen A
Jaspars C
Sintenie JB
Seelen HAM
Brink PRG
Poeze M
Evers SMAA

Injury. 2022;53(2):713-718

Abstract

Objectives

To estimate the economic burden expressed in costs and quality of life of the post-surgical treatment of peri- and/or intra-articular fractures in the lower extremity from a societal perspective.

Design and setting

This is a quantitative study as it aims to find averages and generalize results to wider populations. The design is a cost-of-illness and quality of life study focusing on costs (in euros), Activities of Daily Living (ADL) and Quality of Life (QoL) in patients with peri- and/or intra-articular fractures of the lower extremities.

Surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities during 26 weeks follow-up. Patients were included from 4 hospitals in the Netherlands.

Main outcome measures

Costs, ADL and Quality Adjusted Life Years (QALY).

Methods

Cost of illness was estimated through a bottom-up method. The Dutch EQ-5D-5L questionnaire was used to calculate utilities while Lower Extremity Functional Scale (LEFS) scores were used as a measure of ADL. Non-parametric bootstrapping was used to test for statistical differences in costs. Subgroup analyses were performed to determine the influence of work status and further sensitivity analyses were performed to test the robustness of the results.

Results

Total average societal costs were € 9,836.96 over six months. Unexpectedly, total societal and healthcare costs were lower for patients with a paid job relative to patients without. Sensitivity analyses showed that our choice of a societal perspective and the EuroQoL as our primary utility measurement tool had a significant effect on the outcomes. The ADL at baseline was 10.4 and at 26 weeks post-surgery treatment 49.5. The QoL was at baseline 0.3 and at 26 weeks post-surgery treatment 0.7. These findings are indicative of a significantly improved ADL and QoL ($p < 0.05$) over time.

Conclusions

This study revealed a substantial economic burden in monetary terms and effect on QoL of patients with peri- and/or intra-articular fractures of the lower extremities during 26 weeks follow-up.

Introduction

Every year, millions of people with a fracture of the lower extremities are treated in emergency rooms all over the world.¹ In the Netherlands, approximately 15,000 trauma patients undergo surgery because of peri- and/or intra-articular fractures of the lower extremity.^{2,3}

The standard aftercare treatment in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities features either non-weight bearing or partial weight bearing.⁴ According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Principles of Fracture Management, postoperative management of peri- and/or intra-articular fractures of the lower extremities consists of non-weight bearing for 6-12 weeks, followed by partial weight bearing with a 25% increase in fracture loading every week.⁵ Full weight bearing in this method will be reached generally 10-16 weeks post-surgery.

Recent studies based on protocols using the existing non-weight bearing guidelines have reported composite postoperative complication rates of up to 37% with an average of 10-20% in patients with lower extremity fractures.⁶⁻¹⁵ The complications in trauma patients with peri- and/or intra-articular fractures of the lower extremities have a significant impact on the period of postoperative rehabilitation, suggesting substantial direct health-care costs and economic burden to the society. However, to our knowledge, no study has yet been done regarding the cost-of-illness (Col) in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities.

Insight into the estimation of the economic burden could help to raise awareness in policy makers about the disease and provide relevant information for economic evaluations in the future. The aim of this study was to determine the costs and QoL changes in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities over a 26 weeks period. The medical ethics committee of Maastricht University Medical Center, Maastricht, the Netherlands, approved this study, reference number: METC 16-4-236. Patient's informed consent to participate was obtained from all patients.

Patients and methods

This prospective multicenter cohort study included surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities. Patients were recruited from 4 hospitals in the Netherlands (i.e. Catharina Hospital, Eindhoven;

Elkerliek Hospital, Helmond; Viecuri Medical Center, Venlo; and Maxima Medical Center, Veldhoven) between October 2017 and September 2018, as part of a larger prospective cohort study.¹⁶ The patients were included according to the inclusion and exclusion criteria of the study protocol of Kalmet et al.¹⁶ Surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities (i.e. pelvic fractures, acetabular fractures, distal femur fractures, tibial plateau fractures, pilon fractures, calcaneal fractures and talar fractures) were eligible for inclusion if they were 18 years or older. Patients with pathological fractures, shaft fractures treated with intra-medullary nailing, or fractures treated with external fixation, and patients with amputations of (parts of) the lower extremity, were excluded. Patients with cognitive dysfunction due to a severe neurotrauma or to concomitant (mental) illness were also excluded.¹⁶ All patients underwent a non-weight bearing regime for 6–12 weeks followed by partial weight bearing with a 25% increase in fracture loading every week according to the existing (AO-) guidelines.⁵

The baseline characteristics in the study were collected from the electronic medical records by two researchers (PK and CM) and included: age at time of fracture, gender, ASA (American Society of Anesthesiologists) typology assessing the fitness of patients before surgery, i.e. type 1–6) classification,¹⁷ Charlson-comorbidity score (classifying prognostic comorbidity, a higher score representing additional comorbidities),¹⁸ type of fracture, and the length of stay in hospital (in days).

Primary outcome measures include costs, the Activity of Daily Living (ADL) and the Quality of life (QoL). These were collected through patient questionnaires. Patient-self-perceived outcome questionnaires were taken at baseline, week 2, 6, 12 and 26 post-surgery. The costs were measured in three categories: healthcare costs, productivity costs and patient and family costs. The iMTA (Institute for Medical Technology Assessment) Medical Consumption Questionnaire (iMCQ) was used to measure all healthcare consumption by the participants during each follow-up period and included medication costs, visits with General Practitioners (GP), medical specialists, occupational physicians, therapists (physical therapists, dieticians, occupational therapists, speech therapists, homeopaths and psychologists), social workers, emergency rooms visits, ambulance transportation, hospital admittance, homecare (domestic help, help with ADL and nursing), admittance to rehabilitation centers and admittance to assisted living centers.¹⁹ The iMTA (Institute for Medical Technology Assessment) Productivity Cost Questionnaire (iPCQ) was used to measure work absence and the number of hours the participants were replaced for unpaid work.²⁰ Patient and family costs were estimated with the iMCQ and consisted of travel costs.

Following Dutch guidelines, a bottom-up approach was used for the present study.^{21,22} For the valuation of costs, the reference prices from the Dutch costing

guideline were used.²³ These reference prices were multiplied by the average healthcare consumption as measured with the iMCQ and iPCQ. In accordance with the guidelines, all hours of unpaid work were valued as replaced by paid help.²³ The costs of medication were based on the price per dosage. Prescription costs were added for all medications except for over-the-counter drugs. A distinction was made between first prescriptions (€12) and repeated prescriptions (€6). Costs were, where necessary, indexed for the year 2018.

To check for the potential influence of assumptions made in the analyses, several sensitivity analyses were performed. The choice of the societal perspective was based on Dutch guidelines,²¹ and other validated perspectives,²⁴ societal costs versus healthcare costs were compared. Furthermore, subgroup analyses were performed. The groups were respectively; employed subjects, unemployed subjects, subjects who endured complications during rehabilitation and subjects who did not endure complications during rehabilitation.

The perceived performance in ADL was measured with the Lower Extremity Functional Scale (LEFS). The LEFS consists of 20 questions about a person's ability to perform daily tasks. Each question can be scored from 0 to 4, where 0 represents extreme difficulty to perform the activity. The maximum possible score is 80 points, corresponding to no disability. The lower the score, the greater the disability.²⁵ The QoL was measured with the EuroQol 5-Level EQ-5D questionnaire. The EuroQol 5-Level EQ-5D questionnaire consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension was scored on a five-point scale ranging between no problems and extreme problems.²⁶ Quality Adjusted Life Years (QALYs) were subsequently calculated by multiplying utilities with 26 weeks, resulting in a QALY estimate of 0.23.

The secondary outcome measure was complications after a follow-up of 26 weeks post-surgery. Postoperative complications (e.g. complications related to the fracture and general complications non-related to the fracture) were defined as any adverse event that required intervention within 26 weeks; these were recorded as either present or absent, along with the type of complication.

Economic analysis

All analyses were performed according to the intention-to-treat principle and therefore included all participants. Clinical differences between the patients with a paid job and patients without a paid job were assessed using a linear mixed-effects regression model in SPSS (IBM SPSS Statistics, Version 25.0, Armonk, New York). Due to the random nature of the patient participation, it was decided that no distinction would be made

between fracture and non-fracture related medical consumption, as well as for productivity losses. For the costs, LEFS and the EQ-5D there was no missing data. Therefore, exclusion or extrapolating in case of missing data was not required.

A number of subgroup sensitivity analyses were performed. These analyses were conducted to assess differences between employed and unemployed patients and patients with and without complications. The EQ-5D scores were further used to estimate the QALYs. Base case analysis was conducted from a societal perspective, including patient & family costs and productivity loss costs. As costs data are generally skewed and not distributed normally, non-parametric bootstrap re-sampling techniques were performed to estimate cost uncertainties.

The medical ethics committee of Maastricht University Medical Center+, Maastricht, the Netherlands approved this study and informed consent was obtained from all patients.

Statistical methods

Statistical analyses were performed with IBM SPSS Statistics, Version 25.0, Armonk, New York. For the non-parametric bootstrapping (1000 replications) of the costs, Excel for Mac V.16 was used to extract estimates of the mean and 95%-confidence intervals (CIs).

Descriptive statistics were used to provide an overview of the demographic data and baseline characteristics for the entire study population. Independent samples t-tests were used for normally distributed continuous data and chi-squared tests for categorical variables. Results are presented as either mean \pm standard deviation (SD) or as frequencies and percentages. The level of statistical significance was set at $\alpha=0.05$.

Results

Baseline characteristics

This cohort study included 53 surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities (N=1 pelvic, N=3 acetabular, N=28 tibial plateau, N=12 pilon and N=9 calcaneal), 49.1% of which were male, with a median group age of 60.0 years (IQR 47.0-67.0). N=26 (49.1%) were still active employees. Baseline characteristics of the entire population are presented in Table 4.1. Patients with paid job were significantly more male ($p=0.04$), and significantly younger ($p<0.01$) compared to the patients without paid job. The ASA-classification and the Charlson score were both significantly lower in patients with paid job compared to the patient

without paid job. Furthermore, no differences were found in fracture type, two or more operations and median length of stay in hospital between the two groups.

Table 4.1 Baseline characteristics of the entire population.

	Patients with paid job (N=26)	Patients without paid job (N=27)	Total (N=53)	p
Female, N	9 (34.6%)	16 (59.3%)	27 (50.9%)	0.04
Median age (IQR), years	48.5 (41.3-60.0)	67.0 (58.0-71.0)	60.0 (47.0-67.0)	<0.01
ASA, N				0.02
I, II	25 (96.2%)	19 (70.4%)	44 (83.0%)	
III >	1 (3.8%)	8 (29.6%)	9 (17.0%)	
Median Charlson score (IQR)	1 (0-2)	3 (2-5)	2 (1-3)	<0.01
Fracture type, N:				0.96
Pelvic	0 (0.0%)	1 (3.7%)	1 (1.9%)	
Acetabular	0 (0.0%)	3 (11.1%)	3 (5.7%)	
Tibial plateau	17 (65.4%)	11 (40.7%)	28 (52.8%)	
Pilon	7 (26.9%)	5 (18.5%)	12 (22.6%)	
Calcaneal	2 (7.7%)	7 (25.9%)	9 (17.0%)	
In-hospital outcome:				
Two or more procedures (%)	3 (11.5%)	5 (18.5)	8 (15.1)	0.73
Median length of stay in hospital (IQR), in days	4.0 (2.0-11.0)	6.0 (2.0-15.0)	5.0 (2.0-11.5)	0.16

Abbreviation: N, number of subjects; ASA, American Society of Anesthesiologists; IQR, interquartile range.

Patients' self-perceived outcome measures

After a follow-up of 26 weeks post-surgery, the overall response rate of the patients' self-perceived outcome levels at all measurement points was 100%. The overall mean costs at baseline, collected over a 3 months period before fracture, were €301.33, consisting of 1) mean healthcare costs over a 3 months period before fracture of €227.83; 2) productivity losses over a 4 weeks period before fracture of € 59.72; and 3) patient and family costs before fracture of €13.78. Compared to baseline, the overall mean costs during the 26 weeks of rehabilitation were significantly increased to €9,836.96; consisting of healthcare costs (68.7%); the productivity loss (28.7%), and 3) patient and family costs (2.6%). The costs for the patients with paid job and the patients without paid job are presented in Table 4.2.

There was significantly lower ($p < 0.01$) total mean societal costs and total mean healthcare costs in patients with paid job compared to patients without paid job (Table 4.2). In terms of the ADL and QoL there were differences in the ADL, as measured with the LEFS and no significant difference in the total utility and costs, as measured with the EQ-5D.

Table 4.2 Costs per group in base case and sensitivity analysis scenario.

	Total population (N=53)			Total after 26 weeks
	BS	FU W 0-12	FU W 13-26	
Healthcare (SD)				
Patients with paid job	150.60 (338.43) ^{151.18}	4,413.50 (3,231.64) ^{4,412.89}	701.45 (435.36) ^{693.85 a}	5,114.95 (3,667.00)
Patients without paid job	302.20 (413.20) ^{301.24}	7,479.63 (9,076.19) ^{7,518.62}	861.35 (701.75) ^{861.44 a}	8,340.98 (9,777.94)
Total	227.83 (382.47) ^{228.68}	5,975.49 (6,971.67) ^{6,239.71}	782.91 (586.40) ^{670.04 a}	6,758.40 (7,558.07)
Productivity Loss (SD)				
Patients with paid job	121.75 (465.88) ^{124.18}	3,500.04 (3,462.10) ^{3,506.63}	853.64 (1,707.10) ^{811.88 a}	4,353.68 (5,169.20)
Patients without paid job	0.00 (0.00) ^{0.00}	1,011.87 (1,363.51) ^{1,001.61}	341.70 (555.76) ^{311.11 a}	1,353.57 (1,919.27)
Total	59.72 (328.82) ^{57.44}	2,232.48 (2,875.60) ^{2,222.13}	592.84 (1,273.67) ^{698.83 a}	2,825.32 (4,149.27)
Patient-family (SD)				
Travel	13.78 (33.75) ^{13.64}	133.51 (76.07) ^{133.93}	119.72 (82.60) ^{133.09}	253.23 (158.67)
Total average costs (SD)				
Patients with paid job	285.63 (630.48) ^{282.95}	8,033.02 (4,917.43) ^{8,098.83}	1,661.28 (1,913.36) ^{2,160.18 a}	9,694.30 (6,830.79)
Patients without paid job	316.45 (435.85) ^{321.44}	8,638.52 (9,327.63) ^{8,668.88}	1,335.82 (1,035.01) ^{1,340.20 a}	9,974.34 (10,362.64)
Total	301.33 (535.10) ^{298.46}	8,341.48 (7,431.10) ^{8,326.70}	1,495.48 (1,524.03) ^{1,490.56 a}	9,836.96 (8,955.13)

^a Sig. difference in group between patients with paid job and patients without paid job at 5% level. X Bootstrap Value
Abbreviation: N, number of subjects; SD, standard deviation; BS, baseline; FU, follow-up; W, week. Data in cells are in Euros (€)

Comparing sub-groups based on work status showed a significantly lower mean healthcare costs in patients with paid job compared to patients without paid job. Furthermore, the mean productivity costs were significantly higher in patients with paid job than in the group of patients without paid job. The costs at baseline and during 26 weeks of rehabilitation are presented in detail in Table 4.2. The sub-groups comparison indicated that there were differences in the ADL for both patients with paid jobs as patients without paid jobs. In terms of the utility and costs a difference was only perceived among patients with a paid job (Table 4.3). The LEFS score increased by 29.1 points during the 26 weeks of rehabilitation. The Utility scores increased significantly from 0.3 to 0.7 between 2 and 26 weeks of rehabilitation ($p < 0.01$) (Table 4.3).

Table 4.3 Outcomes base case and sensitivity analysis scenarios.

	FM ^e	FU W6	FU W12	FU W26	p-value
LEFS (SD)					
- LEFS-scores in patients with paid job (N=26)	10.0 (5.1)	15.1 (7.0)	29.5 (14.6)	53.0 (11.4)	<0.01 ^{a, b}
- LEFS-scores in patients without paid job (N=27)	10.9 (3.5)	17.5 (5.1)	35.5 (9.8)	46.3 (14.0)	<0.01 ^{a, b}
- Total LEFS-scores (N=53)	10.4 (4.4)	16.3 (6.2)	32.5 (12.7)	49.5 (13.1)	<0.01 ^{a, b, c}
Utility scores, (SD)					
- Utility-scores in patients with paid job (N=26)	0.3 (0.1)	0.4 (0.1)	0.7 ^d (0.2)	0.8 ^d (0.1)	<0.01 ^b
- Utility-scores in patients without paid job (N=27)	0.3 (0.2)	0.3 (0.2)	0.5 ^d (0.3)	0.7 ^d (0.3)	NS
- Total Utility-scores (N=53)	0.3 (0.2)	0.4 (0.2)	0.6 (0.2)	0.7 (0.2)	NS

^a Significant difference in group between FM and FU W6 at 5% level; ^b Significant difference in group between FU W6 and FU W12 at 5% level; ^c Significant difference in group between FU W12 and FU W26 at 5% level; ^d Significant difference in group between patients with paid job and patients without paid job at 5% level;
Abbreviation: N, number of subjects; SD, standard deviation; FM, First measurement; FU, follow-up; W, week; LEFS, lower extremity functional scale; QALY, quality adjusted life year, NS; not significant.

Patient outcome measures

During the rehabilitation, a total of N=11 (20.8%) fracture related postoperative complications were found (N=6 superficial infections, N=1 deep infection, N=1 non-unions, N=2 secondary dislocation of osteosynthesis material and N=1 early removal of osteosynthesis material due to pain). No significant differences were found in total mean costs between patients with or without complications (Table 4.4).

Table 4.4 Costs during 26 weeks of rehabilitation between patients with and without complications.

Total population N=53	Patients with complications (N=11)	Patients without complications (N=42)	p-value
Costs during 26 weeks of rehabilitation			
Mean healthcare costs, (SD)	6,912.18 (7,518.21)	6,718.13 (7,824.99)	NS
Mean productivity loss costs, (SD)	4,276.85 (5,246.54)	2,541.97 (3,875.43)	NS
Mean patient and family costs, (SD)	217.21 (136.34)	262.66 (164.09)	NS
Mean overall costs, (SD)	11,748.36 (7,517.81)	9,716.61 (8,115.67)	NS

Data in cells are in Euros (€), SD; standard deviation, NS; not significant

Discussion

This study found that the costs of surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities following a non-weight bearing protocol was, on average, €9,836.96 during 26 weeks of rehabilitation. Significant higher costs were observed for patients without a paid job compared to those with paid job. This difference was mainly caused by the healthcare costs of this group. Furthermore, no significant differences in the perceived performance in ADL were observed over the follow up period as measured with the LEFS. This study did observe an improvement of utility over time. Finally, the mean total costs in patients with complications were not significantly different to those of patients without complications.

In our study the majority of the incurred costs during the 26 weeks of rehabilitation were healthcare costs. The healthcare costs accounted for 68.7% of the total costs. The total costs during the 26 weeks of rehabilitation were two times more than the mean healthcare expenses reported in the literature of €4,462.00 per person per year.²⁷ Furthermore, the group of patients without paid job had 2.9% higher total costs than the patients with paid job. Additionally, the group of patients without paid job had 31.1% lower productivity losses and there healthcare costs were significantly higher (61.3%) than the patients with paid job. There were several possible reasons for these outcomes: first, some patients with paid job may have been able to work, paid

and unpaid, despite their fracture, reducing productivity losses. Second, the group of patients without paid job were significantly older, and had significantly more comorbidity than the patients with a paid job, which could explain the increased need of care during rehabilitation.

The treatment as usual regarding postoperative management is 6-12 weeks non-weight bearing.⁵ This protocol is unchanged for 60 years and not based on evidence-based medicine.⁵ Recent studies have added evidence in support of the use of an early or permissive weight bearing protocol.^{4,28,29} According to the present study, the healthcare costs together with the productivity losses represent the majority of the total costs. These costs could be due to the period of non-weight bearing. Recent studies have shown that early or permissive weight bearing might shorten the period of postoperative management,^{4,28,30} and therefore reduce the postoperative costs. However, to our knowledge, there are no studies done investigating the Cost-of-illness nor the cost-effectiveness in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities following different postoperative management. Therefore, we have started a prospective comparative cohort study in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities to address these mitigations.¹⁶

There was a significant clinical improvement in ADL as measured with the LEFS in this study. In our population, the mean LEFS, 26 weeks post-surgery, was 49.5. This is in line with two studies which also reported a significant improvement in ADL in trauma patients after surgery.^{30,31} Furthermore, there was a significant improvement in quality of life between first measurement and week 6 as measured with the EuroQol. Besides, the utility changes in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities haven't been described before. Therefore, this makes it more difficult to compare the utility changes with previous studies.

Recent literature has reported composite postoperative complication rates of up to 37%, with an average of 10–20% in patients with lower extremity fractures (6–15). Comparing our complication data with data published in recent literature, we found comparable rates of postoperative complication (20.8% (N=11/N=53)). The mean overall costs in patients with complications was € 2,031.75 higher than patient without complications. We assume that the increase of the overall costs in patients with complications are representative. However, no literature regarding the costs in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities having complications is available.

This study provides the first recent report on utility outcomes in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities.

Another strength of this study is that a bottom-up approach was used.³² Furthermore, there were no missing data in the follow-up. However, there were some limitations in terms of the interpretation of our data which has to be taken into account. First of all, the use of a questionnaire induces a risk of selection and recall bias. In addition, the time frame of 26 weeks may be too short to detect long term effects on productivity costs. Therefore, further research is needed to mitigate these limitations.

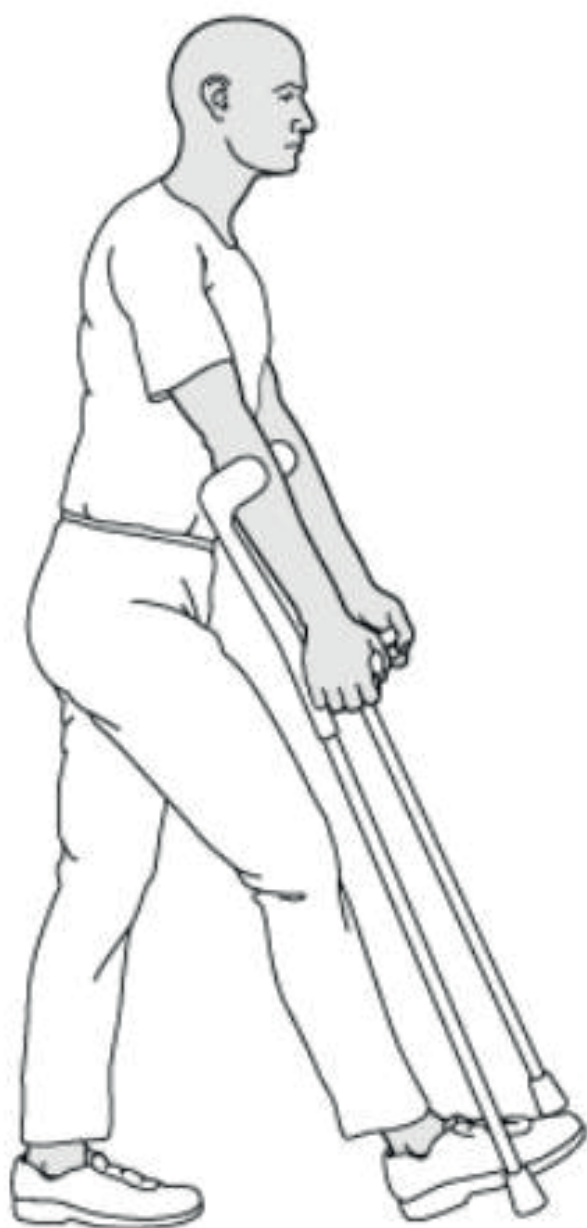
Conclusion

This prospective multicenter study reveal a substantial economic burden in monetary terms and effect on QoL of patients with peri- and/or intra-articular fractures of the lower extremities during 26 weeks follow-up. Total societal and healthcare costs are lower for the patients with a paid job relative to the patients without paid job.

References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. *Injury*. 2006;37:691-7.
2. Landelijk netwerk acute zorg. [National network acute care] Landelijke traumaregistratie [National trauma registry] 2010-2014. The Netherlands. 2015.
3. Landelijk netwerk acute zorg. [National network acute care] Landelijke traumaregistratie [National trauma registry] 2013-2017. The Netherlands. 2018.
4. Haller JM, Potter MQ, Kubiak EN et al. Weight Bearing After a Periarticular Fracture: What is the Evidence? *Orthop Clin N Am*. 2013;44:509-19.
5. Ruedi T, Buckley R, Moran C. AO principles of fracture management. New York: Thieme; 2007.
6. Choo K. Postoperative complications after repair of tibial plateau fractures. *J Knee Surg*. 2014;27:11-20.
7. Hulsker C. Evidence-based treatment of open ankle fractures. *Arch Orthop Trauma Surg*. 2011;131:1545-53.
8. Yu X. Postoperative complications after closed calcaneus fracture treated by open reduction and internal fixation: a review. *J Int Med Res*. 2013;42:14-25.
9. Koval K. Functional outcomes and mortality vary among different types of hip fractures: a function of patient characteristics. *Clin Orthop Relat Res*. 2004;425:64-71.
10. Dong-Hyun L. Comparison of early versus delayed Weightbearing outcomes after microfracture for small to mid-sized Osteochondral lesions of the talus. *Am J Sports Med*. 2012;40(9):2023-8.
11. Jason J. Talar neck fractures: a systematic review of the literature. *J Foot Ankle Surg*. 2013;52(1):56-61.
12. Lasanianos N. Early mobilization after uncomplicated medial subtalar dislocation provides successful functional results. *J Orthop Traumatol*. 2011;12(1):37-43.
13. Mario CK. Early mobilization in bilateral talar fractures. *Foot Ankle Online J*. 2014;7(2):9.
14. Schwabe P. Complications after osteosynthetic treatment of acetabular fractures. *Orthopäde*. 2014;43(1):24-34.
15. Papakostidis C. Pelvic ring disruptions: treatment modalities and analysis of outcomes. *Int Orthop*. 2009;33(2):329-38.
16. Kalmet PHS, Meys G, v. Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surgery*. 2018;18(1).
17. Doyle DJ, Garmon EH. American Society of Anesthesiologists Classification (ASA Class). StatPearls. Treasure Island, FL: Stat-Pearls Publishing StatPearls Publishing LLC; 2018.
18. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40(5):373-83.
19. Institute for Medical Technology Assessment, iMTA. iMTA Medical Consumption Questionnaire (iMCQ) (2019). Available from: <https://www.imta.nl/questionnaires/>
20. Institute for Medical Technology Assessment, iMTA. iMTA Productivity Cost Questionnaire (iPCQ) (2019). Available from: <https://www.imta.nl/questionnaires/>
21. Zorginstituut Nederland. Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg. Diemen: Zorginstituut Nederland; 2016.
22. Tarricone R. Cost-of-illness analysis: What room in health economics? *Health policy*. 2006;77(1):51-63.
23. Zorginstituut Nederland [Dutch Healthcare Institute]. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg [Cost manual: Methodology of cost research and reference prices for economic evaluations in health care]. 2015.
24. Zilberberg MD, Shorr AF. Understanding cost-effectiveness. *Clinical Microbiology and Infection*. 2010;16:1707-12.
25. Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Physical Therapy*. 1999;79:371-83.
26. Herdman M, Gudex C, Lloyd A et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research*. 2011;20(10):1727-36.
27. CBS Statline. Zorguitgaven [health care expenses]; kerncijfers [key rates]: CBS; 2019 Available from: <https://opendata.cbs.nl/statline/#/CBS/nl/dataset/84047NED/table?ts=1561732027456>.

28. Kalmet PHS, Van Horn YY, Sanduleanu S et al. Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study . Arch Orthop Trauma Surg. 2019;139:483-8.
29. Meys G, Kalmet PHS, Sanduleanu S et al. A protocol for permissive weight-bearing during allied health therapy in surgically treated fractures of the pelvis and lower extremities. J Rehabil Med. 2019;51: 290-7.
30. Repo JP. Treatment of compound tibia fracture with microvascular latissimus dorsi flap and the Ilizarov technique: A cross-sectional study of long-term outcomes. Journal of plastic. Reconstructive & Aesthetic Surgery. 2015;69:524-32.
31. Garner MR. Elective removal of implants after open reduction and internal fixation of Tibial Plateau fractures improves clinical outcomes. Arch Orthop Trauma Surg. 2015; 135:1491-6.
32. Onukwugha E, McRae J, Kravetz A et al. Cost-of-Illness Studies: An Updated Review of Current Methods. Pharmacoeconomics. 2016;34:43-58.



Chapter 5

A protocol for permissive weight bearing during allied
health therapy in surgically treated fractures of the
pelvis and the lower extremities

The first experience with 150 patients

Meys G*
Kalmet PHS*
Sanduleanu S
van Horn YY
Maas GJ
Poeze M
Brink PRG
Seelen HAM

* Shared first authorship.

J Rehabil Med. 2019;51(4):290-297

Abstract

Introduction

To optimize rapid clinical recovery and the restoration of function and functionality, permissive weight bearing (PWB) has been designed as a new aftercare mobilization regimen, within the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading. The aim of the present paper is to describe a comprehensive protocol for PWB during allied health therapy and to report on the time to full weight bearing as well as the number of complications in patients with surgically treated fractures of the pelvis and lower extremities undergoing PWB.

Patients and methods

This study included surgically treated trauma patients with (peri)- or intra-articular fractures of the pelvis and lower extremities. A standardized PWB protocol was used for all patients. Time to full weight bearing and number of complications were recorded.

Results

This study included 150 patients, 69% male, with a median age of 48 years (IQR 33.0, 57.0). The median time to full weight bearing was 12.0 weeks (IQR 6.8, 19.2). The complication rate during rehabilitation was 10%.

Conclusion

The PWB protocol, as described, might be beneficial and has potential to be implemented in trauma patients with surgically treated (peri)- or intra-articular fractures of the pelvis and lower extremities.

Introduction

A plethora of evidence is available about open reduction and internal fixation procedures in trauma patients with (peri)- or intra-articular fractures, as well as about the processes involved in bone healing.^{1,2} However, the subsequent rehabilitation treatment, or early aftercare, has been less systematically documented and is often based on empirical, implicit knowledge of individual medical or allied health therapists, acquired throughout many years of clinical practice. No formal evidence-based guidelines are available on the aftercare of surgically treated fractures. In view of this lack of evidence, many orthopedic and trauma surgeons tend to advise conservatively in regards to weight bearing in rehabilitation, and hold on to the prevailing dogmas, i.e. recommending time-contingent progression of weight bearing. Besides, even with specific advice from specialists, patients may not always be committed to complying with non-weight bearing advice.³⁻⁵ It is remarkable that the recommendations for aftercare in patients surgically treated for fractures are still more or less the same as 60 years ago, without any sources of evidence being given for the advice.^{2,6}

Fracture healing is a physiologically complex process.⁷ The pace at which bone formation processes take place, together with the aftercare treatment provided, determine what progression of weight bearing may be applied. Weight bearing dosage is often quantified in terms of percentage of body weight, or expressed in more general terms such as non-weight bearing/partial weight bearing/full weight bearing, without the therapist knowing which weight is actually borne at the level of the osteosynthesis and fracture during both rehabilitation training and daily activities. Despite this fairly ill-defined terminology, few complications due to overloading seem to occur in clinical practice. Nevertheless, both overloading and underloading may lead to a more complicated and extended recovery. A schematic overview of the consequences of loading for the consolidation process is depicted in Figure 5.1. Weight bearing is necessary to elicit micro-movements between adjacent bony fracture components, stimulating biological processes that enhance fracture consolidation, and to minimize negative effects of immobilization.^{8,9}

To optimize rapid clinical recovery and the restoration of function and functionality, it may be useful to apply a treatment protocol that is near the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading. However, no clear evidence on the location of this upper boundary is known from literature. Therapy dosage in the early aftercare treatment of fractures is to a large extent determined by the load bearing capacity of the bone, which in turn depends on the type of fracture, the bone quality, the soft tissue quality, the stabilizing effects of the surrounding soft tissue cuff, the stabilization method used (plaster/nail/plate) as well as the mechanical load bearing capacity, and the point of application and direction

of the forces relative to the line(s) of fracture.^{10,11} However, functional outcome after fracture rehabilitation not only depends on mechanical stability, but also on an intricate complex of bio-psycho-social processes, involving physical tissue damage characteristics of the bone and other surrounding soft tissue, existing co-morbidities, and patients' age, gender, physical and mental condition, as well as their cognitive abilities and coping styles.¹²⁻¹⁴ In ICF terms (International Classification of Functioning, Disability and Health),¹⁵ this means that aftercare treatment should not only focus on the patients' functioning, but also on their activity and participation levels. To date, the literature has reported no comprehensive, ICF-based protocol for the aftercare of patients with a surgically treated fracture that systematically addresses patient's aftercare assessment, selection and provision of aftercare modalities, monitoring of therapy intensity, and evaluation of aftercare.

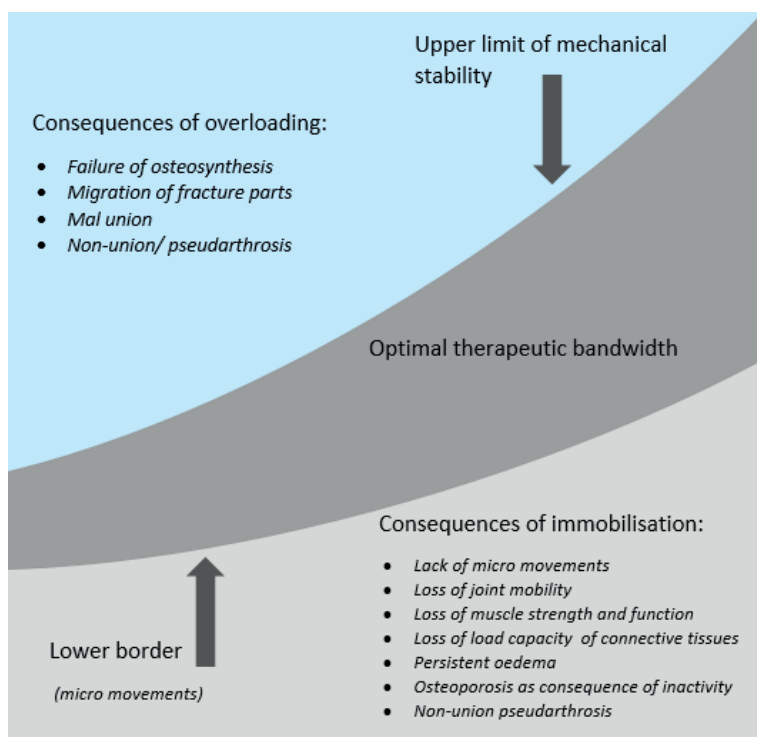


Figure 5.1 Schematic overview of the consequences of loading in the consolidation process.

The aim of the present paper is to describe a comprehensive protocol for permissive weight bearing (PWB) during allied health therapy and to report on both the time to full weight bearing and the number of complications in patients with surgically treated fractures of the pelvis and lower extremities who undergo PWB.

Patients and methods

Basic elements of the protocol

Since PWB was implemented at our rehabilitation center from 2003, and has been standard care since 2005, much experience has been gained in surgically treated trauma patients with (peri)- or intra-articular fractures of the pelvis and lower extremities. During this period, the research group has developed a PROtocol for permissive weight bearing during allied health (paraMEDical in Dutch) Therapy and Evaluation of surgically treated fractUreS (acronym: PROMETHEUS) of the pelvis and lower extremities, which consists of four basic elements, viz. a patient assessment guide, an aftercare aims identification guide, a treatment guide, and a treatment evaluation guide. Figure 5.2 shows a schematic representation of the use of the PROMETHEUS protocol. The fracture aftercare process starts by assessing the patient's profile. Next, the generic and patient-specific treatment aims are identified, which, when combined, lead to the aftercare treatment aims. These aims are then compared with the patient's profile descriptors, which, together with potential predictors of the outcome of the aftercare of the surgically treated fracture, may indicate (a) the feasibility of the aftercare treatment aims, (b) the estimated time frame in which the aims may be reached and (c) the intensity/dosage/weight bearing needed to achieve the aims. Treatment progress and possible complications are assessed using the treatment evaluation guide, and may lead to alteration/adjustment of the treatment plan.

Patient Assessment Guide (PAG)

In addition to a description/classification of fracture(s), this guide consists of a set of patient profile descriptors that have been reported in the clinical literature as being potentially useful in predicting treatment progress and outcome of individual patients during fracture rehabilitation.^{12-14,16} In effect, the guide serves to establish a patient profile, focusing on characteristics promoting or limiting fracture healing, therapy outcome and the occurrence or non-occurrence of complications during fracture healing. The PAG helps draw clinical conclusions on (a) the post-rehabilitation activity level to be expected, thus guiding the selection of attainable aims; (b) therapy intensity; and (c) the risk of complications occurring during the recovery process. Checking each PAG item results in a patient profile. The PAG is depicted in Figure 5.3.

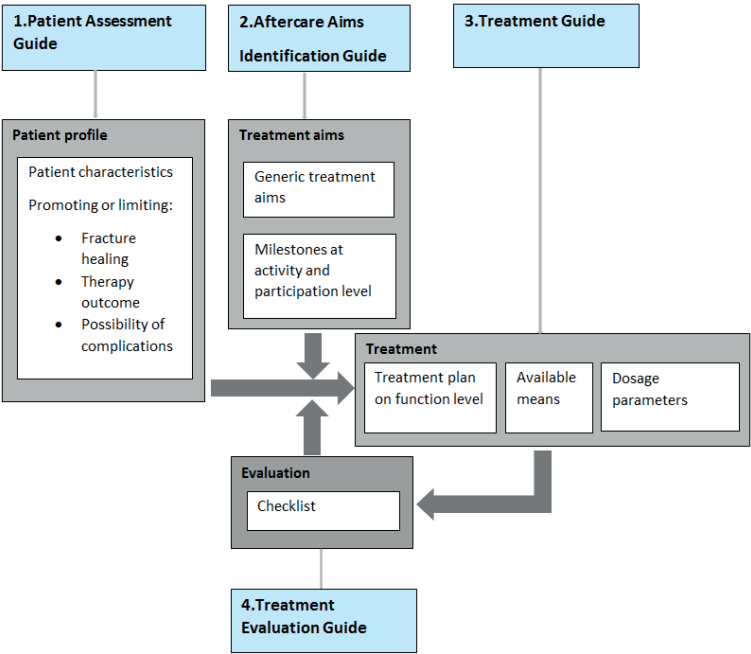


Figure 5.2 Four basic elements of PROMETHEUS.

Aftercare Aims Identification Guide (AAIG)

The AAIG helps to classify patient-defined treatment aims at the activity level (therapy milestones) aimed for during the recovery process. The classification embodies five areas of the ICF classification: mobility, self-care, domestic life, major life areas and social and civic life. The early rehabilitation phase, which primarily aims at stance and ambulation, is subdivided into several sub-phases, of arbitrary length, i.e. with a certain bandwidth, during which weight bearing on the fractured leg is gradually increased with a simultaneous decrease in the use of mobilization-supporting aids, like hydrotherapy, bars or crutches. The change from one sub-phase to the next is gradual and depends on the effectiveness with which the activity is performed by the patient, based on criteria defined in the protocol. Once a therapy milestone has been reached, it is marked and time-stamped in the AAIG, thus providing an overview of the progress of weight bearing at the activity level and the progress of the patient's functional activities. This also enables the therapist to correlate information on the achievement of specific milestones to therapy effects recorded in the Treatment Evaluation Guide (TEG) (see below) and to the possible occurrence of complications. Table 5.1 presents an overview of the AAIG.

Patient profile descriptor			
Name of patient:		Male/Female:	Date of birth:
Fracture date:		Date of surgery:	Date screening
Systemic Factors			
Age			
Informal care in home situation	Yes	No	
Osteoporosis	Yes	No	Unknown
Nutrition status	SNAQ score (Short Nutritional Assessment Questionnaire)		No malnutrition Imminent malnutrition Malnutrition
Albumin levelgram/Litre		
Dehydration	Yes	No	
Anaemia	Yes	No	
Comorbidity	Diabetes Mellitus COPD Chronic Obstructive Pulmonary Disease Cardiac Disease Peripheral Vascular Disease Peripheral Neurological Disease Central Neurological Disease		
Intoxications/Radiation			
Smoking	No	Former Smoker	Recent Smoker
Alcohol	No	More than 2 drinks a day	
Medication	Cytostatics	Description:	
	Corticosteroids	Description:	
	NSAID, Non-Steroidal Anti Inflammatory drugs	Description	
	Immunosuppressives	Description	
Radiotherapy near fracture area	Yes	No	
Trauma related			
Intensive care unit stay	<48 hours	>48 hours	>2 weeks
	Ventilation	No	Yes /during.....Days
High energy trauma	Yes	No	
Multi-trauma	Yes	No	
Number of fractures		
Fracture related			
Fracture 1	Fracture 2	Fracture 3	Fracture.....
Complications	Description		
Infection			
Neurological complication			
Vascular complication			
CRPS (Chronic Regional Pain Syndrome)			
Dislocated fracture parts			
Non-union			
Mal-union			
Delayed union			
Personal characteristics			
Depression	HADS (Hospital Anxiety and Depression)		Depression score
Fear	HADS (Hospital Anxiety and Depression)		Anxiety score
Psychopathology indicator	SCL 90 (Symptom checklist) multidimensional psychopathology indicator		Score
Psychological factor influencing return to work	VAR (Vragenlijst Arbeids Reintegratie*) *(Dutch Questionnaire on Return to Work)		Score
Work (physical workload)	Heavy		Light

Figure 5.3 Patient Assessment Guide.

Table 5.1 An overview of the aftercare aims identification guide.

Rehabilitation Milestones		Progression					
Mobility	Activity	Level of performance					
		Wheel-chair	Symmetric standing with support	Symmetric standing without support	Performing in standing position	One leg stand 1 be > 10sec.	
	Standing						
		Wheel-chair	Walking between bars	Two crutches 2-point gait	Two crutches 4-point gait	Two walking sticks	1 walking stick
	Walking						Without support
	Walking uphill / downhill						
	Moving objects						
	Walking over uneven surface						
	Walking stairs						
Achieved							
Running, climbing, jumping							
Full bed mobility							
Sitting transfers (low level)							
Standing transfer (high level)							
Car transfer							
Moving indoors in adapted environment							
Moving indoors in non-adapted environment							
Performing in standing position							
Picking up an object from the floor							
Cycling (road safety)							
Using public transport							
Driving vehicle							

Table 5.1 (continued)

Rehabilitation Milestones		Progression
Self-care	Washing oneself	
	Care of body parts	
	Going to the toilet	
	Dressing/undressing oneself	
	Putting shoes on/off	
	Drinking independently	
Domestic life	Eating independently	
	Shopping	
	Preparing meals	
	Washing and drying clothes	
	Cleaning house	
	Operating household equipment	
	Storage of daily amenities	
	Removal of waste	
	Gardening	
	Resuming training	
Major life areas, social and civic life	Resuming work	
	Starting / resuming social life	
	Visiting	
	Going out	

Treatment Guide (TG)

The TG (Figure 5.4) aids in designing the treatment plan, i.e. selecting the means necessary to attain the treatment aims (at all three ICF levels) and the appropriate dosage of each of these means. In the early post-surgery rehabilitation phase, i.e. until the time when full weight may be borne by the patient, the patients' treatment aims at the function/impairment and activity levels are, in general, similar for fractures of the pelvis and the acetabulum and other fractures of the lower extremities. At the function level, these rehabilitation aims are: control of edema and hydrops, improvement of circulation, maintenance or improvement of mobility of the joint and the adjacent joints, as well as improvement of muscle function, endurance, and coordination. (See also Figure 5.4 "select means"). Aims at the activity level are: performing all transfers necessary, maintaining stance, walking with and without aids, dressing and grooming. The purpose is to have the patient functioning independently (preferably without compensations) as soon as possible. The generic protocol designates the activities of "stance", "walking", and "transfers" as "milestones" (see also the AAIG in Figure 5.2), because they have an inherent relationship to the load bearing capacity of the fracture and can be translated into objectively quantifiable data representing the increase in the patient's weight bearing tolerance.

Treatment Evaluation Guide (TEG)

Ideally, the increase in load bearing by the fracture takes place in parallel to fracture healing. In order to approximate this condition, the gradual increase in weight borne by the fracture is guided by the concurrent clinical symptoms. These symptoms are used to evaluate the progress during the rehabilitation treatment, based on the patient's clinical manifestations and reactions to the therapy provided, as well as on the early signs or occurrence of possible complications that may necessitate adjustment of the therapy regime. The aim is to assess whether the therapy dosage is within the optimal therapeutic bandwidth throughout the aftercare process. The TEG screens for the possible effects of weight bearing and for possible complications, using a number of clinical criteria and/or phenomena, i.e. pain (or changes in pain), temperature, erythema, edema, hydrops, neurovascular signs, clinical control of bone alignment, instability, clinical weight bearing capacity, control of adjacent soft tissue and control of mobility of adjacent joints, wounds, the patient's therapy compliance, and changes in medication. Furthermore, if complications such as infection, neurovascular issues, complex regional pain syndrome, failure of the osteosynthesis, and delayed union or non-union occur, these have to be evaluated and graded by the rehabilitation physician or the surgeon in charge. Depending on the outcome of this evaluation, a decision is made to continue the current therapy regime, to adjust it or to consult a medical specialist.

Select treatment aim	Select body region	Select means	Select intensity
Edema circulation	Option menu	Option menu	Option menu
	<input type="radio"/> Shoulder	Active means	Dosage 1
	<input type="radio"/> Elbow	<input type="radio"/> Walking	<input type="radio"/> Seconds
	<input type="radio"/> Wrist	<input type="radio"/> Home trainer	<input type="radio"/> Minutes
Muscle strength/function	<input type="radio"/> Hand	<input type="radio"/> Leg press	<input type="radio"/> Hours
	<input type="radio"/> Spine	<input type="radio"/> Squat	<input type="radio"/> RPM/ (Rounds per minute)
	<input type="radio"/> Pelvis	<input type="radio"/> Leg extension	<input type="radio"/> Watt
	<input type="radio"/> Hip	<input type="radio"/> Leg curl	<input type="radio"/> Kg (Kilograms)
	<input type="radio"/> Knee	<input type="radio"/> Rowing	<input type="radio"/> Sets
Range of motion	<input type="radio"/> Ankle	<input type="radio"/> Swim	<input type="radio"/> Series
	<input type="radio"/> Foot	<input type="radio"/> Step	<input type="radio"/> Repetitions/series/
	<input type="radio"/> Total Body	<input type="radio"/> Hydrotherapy	Intensity/Frequency/week
	<input type="radio"/> Other....	<input type="radio"/> Cross-trainer	<input type="radio"/> Meter
Motor control		<input type="radio"/> Cycling outside	<input type="radio"/> Steps
		<input type="radio"/> Treadmill	<input type="radio"/> Pain level:
		<input type="radio"/> Other....	<input type="radio"/> Below threshold
			<input type="radio"/> At threshold
			<input type="radio"/> Beyond threshold
Cardio/pulmonary		Option Menu	<input type="radio"/> Repetitions/series/
		Passive Means	Intensity/Freq.-week
		<input type="radio"/> CPM (Constant Passive Movement)	<input type="radio"/> Meter
		<input type="radio"/> Orthotics	<input type="radio"/> Steps
		<input type="radio"/> Manual therapy	<input type="radio"/> Pain level:
		<input type="radio"/> Traction, translation	<input type="radio"/> Below threshold
		<input type="radio"/> Angular mobilization	<input type="radio"/> At threshold
		<input type="radio"/> Technics	<input type="radio"/> Beyond threshold
		<input type="radio"/> Other....	threshold
			<input type="radio"/> Other....
Other...			

Figure 5.4 Treatment Guide.

Permissive weight bearing is operationalized in daily practice as follows

First a patient profile is established by filling out the patient assessment guide (Figure 5.3). This results in a comprehensive overview of patient and lesion characteristics that need to be taken into account when setting up a personalized rehabilitation treatment plan. Complications are gauged/inventoried in order to be able to adequately adjust the treatment plan when complications occur. Subsequently, the treatment guide (Figure 5.4) assists the therapist in choosing the appropriate means and training intensities/dosages for setting up the aforementioned personalized training plan.

During the actual treatment phase, a gradual progression in functional activities guided by the subjective experience (pain and confidence of to bear weight) and by objective clinical symptoms of the patient occurring during the process of

rehabilitation. Symptoms as the evolution of signs of inflammation , neuro-vascular status, weight bearing tolerance, possible changes in alignment of the affected side of the body, quality and function of the soft tissue and involved joints.

The progression in functional activities is determined on the basis of the quality of the performance of a functional activity and established in milestones to be achieved at activity level within the ICF areas: mobility, self-care, household, participation, transport (Table 5.1).

The therapy progress is not determined by the degree of loading the affected side of the body in kg or in percentage of the body weight because that, as discussed earlier, is an unrealistic representation of reality. When applying the permissive weight bearing method, conscious choices are made to assess the maximum weight bearing capacity of the fixed fracture and the damaged soft tissue. Within this process, we strive towards allowing the patient to apply the activities (formulated in the request for help (see table 1: aftercare aims identification guide)) with normal/optimal motor skills as quickly as possible. If necessary, these activities may be supported with walking aids and orthoses. The quality of the performance of the activity and safety (e.g. preventing stumbling) are leading in this approach. Progress is determined by the quality with which the activity is carried out and is recorded in the list with therapy milestones (see Table 5.1) based on decreasing the use of walking aids. These walking aids contribute to the quality of the gait pattern and to safety and may possibly compensate for a certain limitation in the patient's conditional capacities such as reduced muscle strength, stability or postural balance reactions. The milestone is only reached if the gait pattern is executed optimally, i.e. resembling normal gait as good as possible, and can be performed independently and safely by the patient. In case of delayed recovery or permanent impairment (due to e.g. complications during rehabilitation), a choice must be made for the best possible gait pattern, optimal for each individual patient. It should include the following aspects:

- Safety: reducing the risk of falls.
- Distance: achieving a functional walking distance for the patient.
- Speed: achieving an acceptable functional walking speed.
- Prevention: the chosen strategy with regard to the gait pattern must be a sustainable solution to compensate for the possible physical restrictions and fit the mental and physical capacity of the patient. The aim is to reduce the risk of injury due to e.g. overload.
- Variability: the patient is able to adapt his gait to the environmental conditions given.
- Visual acceptable: the gait pattern looks acceptable for the patient

In case of limited conditional abilities such as lack of joint mobility, muscle strength, joint stability, endurance and/or postural balance, trade-offs have to be made regarding the above items. The patient will have to give a priority as to which of the above aspects are most important to him.

Pilot study

In order to assess the level of weight bearing and the rate of complications when using the PROMETHEUS protocol, a pilot study was conducted in 2015, which included surgically treated trauma patients with (peri)- or intra-articular fractures of the pelvis and lower extremities who were admitted to our rehabilitation center between 2005 and 2015.

Patients with pathological fractures, shaft fractures treated with intra-medullary nailing, or fractures treated with external fixation, and patients with amputations in the area of the lower extremity, were excluded. Also excluded were patients with cognitive dysfunction, due to the consequences of a severe neurotrauma or to concomitant or drug-based mental illness.

All data in the study were collected retrospectively from the electronic patient records, by one researcher. Demographics of patients retrieved included age, gender, date of accident, type of fracture and type of fixation.

Primary outcome measures included the time from surgery till full weight bearing and the total number and type of complications at 1-year follow-up. Type of complications were defined separately, comprising adverse events that occurred during one year of the PWB regime. The rate of individual complications was also recorded.

The medical ethics committee approved this study, and informed consent was given by all patients.

Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics, Version 23.0, Armonk, New York. Descriptive statistics were used to describe the demographic data and baseline characteristics of the entire population. Results are presented as frequencies and percentages. Data are described as median values, interquartile ranges [x,y] and the minimum and the maximum [min-max]. Binary logistic regression was performed to assess independent predictors of late full weight bearing (>12 weeks) throughout both PWB and RWB groups. The level of statistical significance was set at $\alpha=0.05$.

Results

Baseline characteristics

This pilot study included 150 patients, of whom 68.7% were male, with a median age of 48 years ([IQR 33.0, 57.0], [range: 15-77 years]). The sample included different types of surgically treated (peri)- or intra-articular fractures of the pelvis and lower extremities from the pelvis to the foot. Baseline characteristics are presented in Table 5.2. In all, N=124 (82.7%) of the patients had two or more fractures, and N=19 patients (12.7%) suffered from head injuries. In total, 201 lower extremity fractures were identified, which can be divided into 5 subtypes: pelvic/acetabular (N=76), distal femoral metaphysis or (peri)-articular distal femur (N=42), tibial plateau (N=31), distal tibia/ankle (N=31), and foot (talus, calcaneus) (N=21).

Table 5.2 Baseline characteristics of total sample.

	Total N=150
Female	47 (31.3%)
Median age (years) ([IQR], [min-max])	48 ([33.0, 57.0], [15-77])
≥2 fractures	124 (82.7%)
Head injury	19 (12.7%)
Fracture type:	
Pelvic/acetabular	76 (37.8%)
Distal femur	42 (20.9%)
Tibial plateau	31 (15.4%)
Distal tibia/ankle	31 (15.4%)
Foot	21 (10.4%)
Total number of fractures	201

IQR= interquartile range.

Process outcome measures

The median time from fracture surgery to the start of PWB was 2.0 weeks ([IQR 2.0, 3.3], [0-9]). Fifty-two percent of the patients (N=78) reached full weight bearing within 12 weeks. The median time to full weight bearing was 12.0 weeks ([IQR 6.8, 19.2], [2-52]). Table 5.3 specifies for each group of fractures the median and percentage of patients reaching full weight bearing.

Patient outcome measures

The complication rate during postoperative rehabilitation was 10.0% (N=15) of all patients included. Most complications involved non-unions (N=5), wound infections (N=4) or early removal of implants (N=3) because of pain and/or infection. There was

one implant failure and no secondary dislocations. The numbers and types of complications are presented in Table 5.4, specified for each fracture category.

Table 5.3 Time to full weight bearing for specific fracture types.

N=150	Pelvic/ acetabular fractures	Distal femur fractures	Tibial plateau fractures	Distal tibia/ankle fractures	Foot fractures	Total population
Median time to full weight bearing (Weeks ([IQR], [min-max]))	12.6 ([6.0, 18.9], [2-52])	9.1 ([6.0, 17.3], [3-52])	15.0 ([9.7, 20.0], [2-43])	14.0 ([5.7, 24.0], [3-43])	17.0 ([7.0, 24.8], [3-48])	12.0 ([6.8, 19.2], [2-52])
Full weight bearing within 12 weeks	50.0%	61.9%	45.2%	45.2%	42.9%	52.0%

IQR= interquartile range

Table 5.4 Number of fractures and types of complications.

	Pelvic/ acetabular fractures (N=76)	Distal femur fractures (N=42)	Tibial plateau (N=31)	Distal tibia/ankle fractures (N=31)	Foot fractures (N=21)	Total no. fractures (N=201)
Total complications	3	7	3	1	1	15
% per no. fractures	(3.9%)	(16.7%)	(6.5%)	(3.2%)	(4.8%)	(7.5%)
% per no. (N=150) patients	(2.0%)	(4.7%)	(1.3%)	(0.7%)	(0.7%)	(10.0%)
Type of complication						
-Non-union	1	3	1	0	0	5
-Infection	2	1	1	0	0	4
-Removal OSM	0	0	1	1	1	3
-Avascular necrosis	0	1	0	0	0	1
-Periprosthetic fracture	0	1	0	0	0	1
-Implant failure	0	1	0	0	0	1

No.= number of.

Discussion

This pilot study found that 52% of the patients with surgically stabilized (peri)- or intra-articular fractures using a PWB regime according to our in-house PROMETHEUS protocol were able to walk with full weight bearing within 12 weeks, indicating a mean shortening of 4 weeks compared to the current AO- guidelines.² The total complication rate with permissive weight bearing was 10.0%. The fact that about half of the patients in our study did not reach full weight bearing within 12 weeks might be due to hospitalization delay and the high comorbidity rate in our sample.

From a clinical point of view, the PROMETHEUS framework has been designed to be able to systematically, transparently, and falsifiably plan, implement and evaluate/measure patient-tailored allied health aftercare for surgically treated patients with fractures of the pelvis and the lower extremities, starting from the post-surgery phase and extending to the full weight bearing phase and into activities of daily living. The protocol also facilitates the systematic collection of clinically relevant data (clinimetrics) that may guide the gradual (rather than stepwise) progression of the dosage of weight bearing and therapy (based on the patient's current clinical manifestations), as well as assessing complications or their prevention, and facilitating the setting of realistic rehabilitation aims. Initially, the patient's characteristics, potential predictors of fracture consolidation and risks of complications are identified. During the protocolized treatment process, clinical symptoms are screened at the beginning of each therapy session, using the checklist to establish to what level weight bearing and therapy intensity may proceed. It also identifies early warning signs as to possible complications like failures of the osteosynthesis material, bone alignment problems, non-unions, or infections. Data regarding treatment aims, means used, dosage, milestones achieved at the ICF activity level, etc. are recorded systematically.

The more scientifically relevant reason for developing a systematic and comprehensive protocol was the fact that, despite major improvements in surgical treatment and osteosynthesis materials, rehabilitation aftercare after surgical treatment of fractures has remained almost unchanged over the last six decades.

The PROMETHEUS protocol has been developed in close cooperation between rehabilitation specialists, allied health staff and trauma surgeons. It should serve as a general reference framework and starting point for a discussion of the systematic optimization of allied health aftercare in patients with surgically treated fractures, rather than as a library of predefined standard solutions.¹⁷

It is widely assumed by surgeons that the fixation of pelvic and lower extremity fractures should not be absolutely rigid when physiological forces act on the bones during early weight bearing.¹⁸ One of the key objections to allowing early weight bearing is the possibility of fracture displacement.¹⁹ On the other hand, various authors, including those of more recent randomized controlled trials, have stated that weight bearing does not pose an undue risk of complications or produce poorer outcomes than non-weight bearing protocols.²⁰ These two statements are contradictory and require further evaluation.

To our knowledge there have been no studies on early PWB and its complications during rehabilitation from (peri)- or intra-articular fractures of the pelvis and lower extremities treated with internal fixation. Recent literature has reported composite

postoperative complication rates of up to 37% (range 0.7%-37%).²¹⁻³⁰ A comparison of our complication data with published data based on applying the current guidelines shows comparable rates of complication for all our groups treated with the PWB protocol.²¹⁻³⁰

To our knowledge, no study has found any difference in fracture displacement or healing between early and late weight bearing regimes using radio-isometric analysis. One study of ankle fractures did find a small (0.4 mm) widening of the talar mortise, but this had no clinical or functional significance.³¹ The participants of the study had stable, anatomically adequate fixation of the distal fibula and/or medial malleolus prior to being included in the trials. Recent studies on early weight bearing of surgically treated fractures of the ankle joint showed good outcome and even a lower rate of plate removal.^{31,32} In one radiostereometric study with fractures of the tibial plateau, the mean cranio-caudal migration of the fracture fragments at one year after the start of early weight bearing was insignificantly -0.34 mm (-1.64 to 1.51).³³ This case series showed that in the Schatzker type II fractures that were investigated, internal fixation with subchondral screws and a buttress plate provided enough stability to allow post-operative permissive weight bearing, without harmful consequences.³³ While a certain minimum level of loading is required to elicit micro-movements between adjacent bony fracture components, stimulating the biological processes that enhance fracture consolidation and minimizing the effects of immobilization,^{4,8} both over- and under-loading may lead to prolonged and complicated recovery.

While instructions for rehabilitation given to patients may be clear, patient compliance with a non-weight bearing or limited weight bearing regime has been found to be poor.^{34,35} A number of studies found that patients had actually exceeded the prescribed amount of partial weight bearing even though their self-reported compliance was high.^{35,36} For example, Braun et al used for their study a continuously measuring pedobarography insole to measure the weight bearing in trauma patient with fractures of the lower extremities. The study showed that, despite physical therapy training, weight-bearing compliance to recommended limits was low.³⁶ Overall, despite their willingness to comply, patients often do not adhere to the suggested restrictions on weight bearing and increase their weight bearing as fracture healing progresses.

To optimize recovery with a minimal complication rate, we recommend a treatment that is near the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading, and this treatment is a key component of our PROMETHEUS protocol.

The lack of evidence on aftercare protocols and on permissive weight bearing was the reason to design the PROMETHEUS protocol. In this study a description of a comprehensive protocol for permissive weight bearing has been presented as well as data on both time to full weight bearing and the number of complications in patients with surgically treated fractures of the pelvis and lower extremities. This pilot study is in our opinion quintessential for estimating the sample size in future prospective trials and for gaining insight into the heterogeneity that exists within and between different kind of fractures of the lower extremity with regard to time to full weight bearing and number of complications. However, limitations in our study include the retrospective nature of the study and, due to this retrospection, not taking into account surgeon-oriented functional outcome scores (e.g. knee function) or generic patient satisfaction scores. Furthermore, no radiological controls have been done to investigate the alignment of the fractures and the fracture healing. Another limitation of the study is the lack of monitoring patient compliance.

To mitigate the aforementioned limitations, and to find out whether a PWB protocol results in more favorable process outcomes and patient outcomes, further research is required to establish the added value in terms of effectiveness and cost-effectiveness. To that aim, we have started a prospective cohort study with a control group, also including patient-reported outcome measures to cover the appropriate ICF levels.³⁷

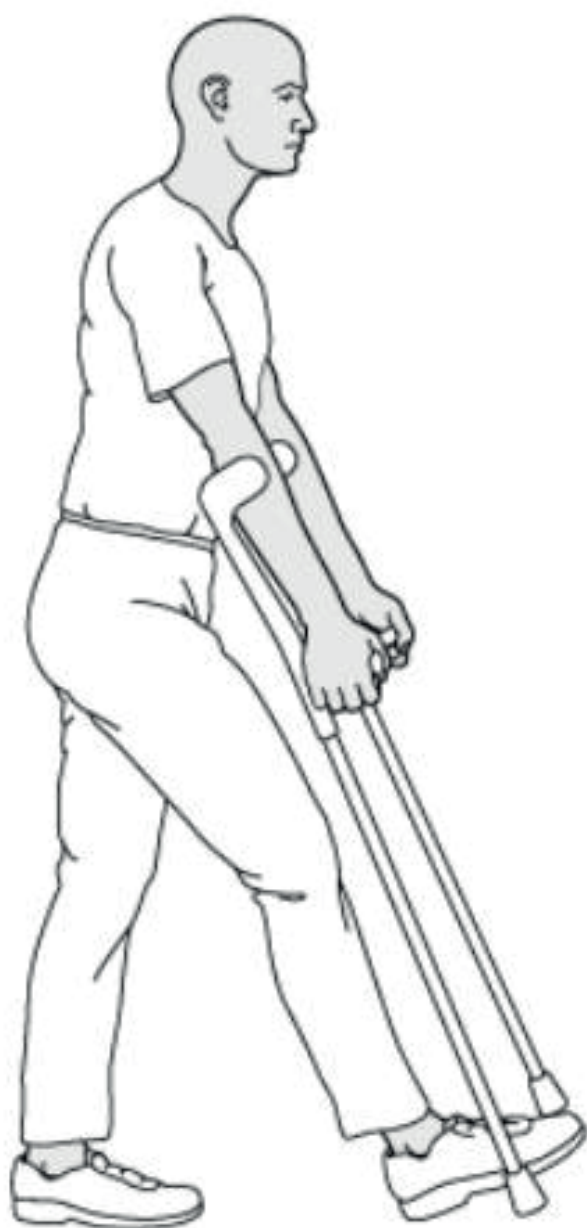
Conclusion

The PROMETHEUS protocol is a patient tailored permissive weight bearing protocol. Given the low complication rate, the protocol might be beneficial to implement in the treatment of trauma patients with surgically treated articular or (peri)- or intra-articular fractures of the pelvis and lower extremities.

References

1. AO Foundation. 2014. Available from: www.aofoundation.org.
2. Ruedi TP, Buckley RE, Moran CG. AO Principles of Fracture Management. Thieme, New York. Third Edition. 2018.
3. Gray FB, Gray C, McClanahan JW. Assessing the accuracy of partial weight-bearing instruction. *Am J Orthop* (Belle Mead NJ). 1998;27: 558-60.
4. Hurkmans HL, Bussmann JB, Selles RW et al. The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy: long-term vertical force measurements inside and outside the hospital. *Arch Phys Med Rehabil*. 2007;88:200-6.
5. Tveit M, Kärrholm J. Low effectiveness of prescribed partial weight bearing. Continuous recording of vertical loads using a new pressure-sensitive insole. *J Rehabil Med*. 2001;33:42-6.
6. Muller ME, Allgower M, Schneider R, Willenegger H. Manual of Internal Fixation Techniques. Springer, Berlin. 1977
7. Wheelless CR. Wheelless' Textbook of Orthopaedics Durham, NC: Duke University Medical Center's Division of Orthopaedic Surgery, and Data Trace Internet Publishing. 2014. Available from: <http://www.wheellesonline.com>.
8. de Morree JJ. Dynamiek van het menselijk bindweefsel [Dynamics of human connective tissue]. Bohn Stafleu van Loghum, Houten, the Netherlands. 2009.
9. Magee DJ, Zachazewski JE, Quillen WS. Scientific Foundations and Principles of Practice in Musculoskeletal Rehabilitation. Saunders Elsevier, St. Louis. 2007.
10. Tencer AF, Johnson KD. Biomechanics in Orthopedic Trauma. Lippincott, Philadelphia. 1994.
11. Court-Brown CM, JD Heckman, McQueen MM et al. Rockwood and Green's Fractures in Adults. Eighth edition. Lippincott Williams & Wilkins, Philadelphia. 2005.
12. Gaston MS, Simpson AH. Inhibition of fracture healing. *J Bone Joint Surg Br*. 2007;89:1553-60.
13. Hernandez RK, Do TP, Critchlow CW et al. Patient-related risk factors for fracture-healing complications in the United Kingdom General Practice Research Database. *Acta Orthop*. 2012;83:653-60.
14. Massari L, Falez F, Lorusso V et al. Can a combination of different risk factors be correlated with leg fracture healing time? *J Orthop Traumatol*. 2013;14:51-7.
15. World_Health_Organisation. International Classification of Functioning, Disability and Health (ICF): WHO]. Available from: <http://www.who.int/classifications/icf/en/>.
16. Hurkmans HL, Bussmann JB, Benda E et al. Predictors of partial weight-bearing performance after total hip arthroplasty. *J Rehabil Med*. 2010;42:42-8.
17. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthop Clin North Am*. 2013;44:509-19.
18. Thomas G, Whalley H, Modi C. Early mobilization of operatively fixed ankle fractures: a systematic review. *Foot Ankle Int*. 2009;30:666-74.
19. Black JD, Bhavikatti M, Al-Hadithy N et al. Early weight-bearing in operatively fixed ankle fractures: A systematic review. *Foot*. 2013;23:78-85.
20. Swart E, Bezhani H, Greisberg J, Vosseller JT. How long should patients be kept non-weight bearing after ankle fracture fixation? A survey of OTA and AOFAS members. *Injury*. 2015;46:1127-30.
21. Choo KL, Morshed S. Postoperative complications after repair of tibial plateau fractures. *J Knee Surg*. 2014;27:11-9.
22. Cornwall R, Gilbert MS, Koval KJ et al. Functional outcomes and mortality vary among different types of hip fractures: a function of patient characteristics. *Clin Orthop Relat Res*. 2004;425:64-71.
23. Lee DH, Lee KB, Jung ST et al. Comparison of Early Versus Delayed Weightbearing Outcomes After Microfracture for Small to Midsized Osteochondral Lesions of the Talus. *Am J Sports Med*. 2012;40:2023-8.
24. Hulsker CC, Kleinvelde S, Zonnenberg CB et al. Evidence-based treatment of open ankle fractures. *Arch Orthop Trauma Surg*. 2011;131:1545-53.
25. Halvorson JJ, Winter SB, Teasdall RD, Scott AT. Talar Neck Fractures: A Systematic Review of the Literature. *J Foot Ankle Surg*. 2013;52:56-61.

26. Lasanianos NG, Lyras DN, Mouzopoulos G et al. Early mobilization after uncomplicated medial subtalar dislocation provides successful functional results. *J Orthop Traumatol.* 2011;12:37-43.
27. Cala M, Barreiro K, Jeffry H. Early mobilization in bilateral talar fractures. *The Foot and Ankle Online Journal.* 2014;7:9.
28. Yu X, Pang QJ, Chen L et al. Postoperative complications after closed calcaneus fracture treated by open reduction and internal fixation: a review. *J Int Med Res.* 2014;42:17-25.
29. Schwabe P, Wichlas F, Druschel C et al. Komplikationen nach osteosynthetischer Versorgung von Azetabulumfrakturen [Complications after osteosynthetic treatment of acetabular fractures]. *Orthopade.* 2014;43:24-34.
30. Papakostidis C, Kanakaris NK, Kontakis G, Giannoudis PV. Pelvic ring disruptions: treatment modalities and analysis of outcomes. *Int Orthop.* 2009;33:329-38.
31. Ahl T, Dalén N, Selvik G. Mobilization after operation of ankle fractures. Good results of early motion and weight bearing. *Acta Orthop Scand.* 1988;59:302-6.
32. Dehghan N, McKee MD, Jenkinson RJ et al. Early Weightbearing and Range of Motion Versus Non-Weightbearing and Immobilization After Open Reduction and Internal Fixation of Unstable Ankle Fractures: A Randomized Controlled Trial. *J Orthop Trauma.* 2016;30:345-52.
33. Solomon LB, Callary SA, Stevenson AW et al. Weight-bearing-induced displacement and migration over time of fracture fragments following split depression fractures of the lateral tibial plateau. *J Bone Joint Surg Br.* 2011;93:817-23.
34. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics.* 2012;35:e31-7.
35. Warren CG, Lehmann JF. Training procedures and biofeedback methods to achieve controlled partial weight bearing: An assessment. *Arch Phys Med Rehabil.* 1975;56:449-55.
36. Braun BJ, Veith NT, Rollmann M et al. Weight-bearing recommendations after operative fracture treatment-fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole. *Int Orthop.* 2017;41:1507-12.
37. Kalmet PHS, Meys G, v. Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg.* 2018;18:8.



Chapter 6

Patient-reported quality of life and pain after
permissive weight bearing in surgically treated trauma
patients with tibial plateau fractures: a retrospective
cohort study

Kalmet PHS
van Horn YY
Sanduleanu S
Seelen HAM
Brink PRG
Poeze M

Arch Orthop Trauma Surg. 2019;139(4):483-488

Abstract

Introduction

A Dutch survey among orthopedic surgeons and trauma surgeons showed that almost 90% of the surgeons do not follow protocols regarding the weight bearing aftercare for tibial plateau fractures. Clinical studies comparing permissive weight bearing (PWB) versus restricted weight bearing (RWB) after surgically treated tibial plateau fractures are not available. The aim of this study was to inventory potential differences in quality of life and pain, and number of complications in patients with surgically treated tibial plateau fractures who followed a PWB regime, relative to those that followed a RWB regime.

Materials and methods

This retrospective cohort study included surgically treated trauma patients with tibial plateau fractures, who underwent rehabilitation according to PWB or RWB between 2005 and 2015. Data such as demographics, patient-reported quality of life and pain, and patient outcome were collected.

Results

This cohort study included 91 patients with a tibial plateau fracture (31 and 60 patients in the PWB and RWB groups respectively). No significant between-group differences in either age or gender were found. However, a significant difference in fracture type was found between groups, ($p = 0.04$). No significant differences were found in either patient-reported SF-12 or VAS scores between the PWB group and RWB group. Time to full weight bearing was significantly shorter in the PWB than in the RWB group, i.e., 14.7 versus 20.7 weeks, ($p = 0.02$). No significant differences were found regarding postoperative complications between the PWB and the RWB groups, i.e., 6.5% versus 10.0%, respectively.

Conclusion

PWB after surgically treated tibial plateau fractures is safe and is related to a significantly reduced time to full weight bearing with no significant differences in patient-reported quality of life and pain or complication rates.

Introduction

The incidence of patients with tibial plateau fractures is approximately 13.3 per 100,000.¹ Protocols for postoperative management of tibial plateau fractures were formulated about 60 years ago and suggest non- or partial weight bearing.² A survey about the adherence of current protocols showed that almost 90% of the surgeons do not follow these protocols standardly regarding the weight bearing aftercare for tibial plateau fractures.³ In addition, patient's compliance to a non- or partial weight bearing regimen is found to be poor and highly depending on the age of the patient.^{4,5} Elderly patients seem to be unable to maintain weight-bearing restrictions.⁶ Thus, patients are likely to start weight bearing in an earlier phase than prescribed in current protocols.

The postoperative management of these surgically treated tibial plateau fractures in trauma patients is also very important regarding the functional outcome. The average overall postoperative complication rate in tibial plateau fractures, combining implant failures, secondary dislocation, non-union and infections into a composite end point, is around 4-27% according to literature.⁷⁻¹⁴

The standard aftercare treatment in surgically treated trauma patients with fractures of the tibial plateau features is non- or partial weight bearing.¹⁵ According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) principles of fracture management, postoperative management of tibial plateau fractures generally consists of toe-touch weight bearing for 6–8 weeks. As to fractures caused by extremely high energy impact, these patients may need to adhere to toe-touch weight bearing regimen for 10–12 weeks.² There is currently no consensus among surgeons worldwide with regard to early weight bearing (i.e. permissive weight bearing) versus restricted weight bearing in surgically treated trauma patients with fractures of the tibial plateau.¹⁶

Biomechanical and animal studies indicate that early weight bearing is beneficial,¹⁷⁻¹⁹ but high-quality clinical studies comparing permissive weight bearing (PWB) versus restricted weight bearing (RWB) after surgically treated tibial plateau fractures are scarce.

The aim of the present study was to inventory potential differences in quality of life and pain, and number of complications in patients with surgically treated tibial plateau fractures who followed a permissive weight bearing regime, relative to those that followed a restricted weight bearing regime.

Patients and methods

This retrospective cohort study included surgically treated trauma patients with tibial plateau fractures at Maastricht University Medical Center+, the Netherlands, who underwent aftercare according to the PWB or a RWB protocol between 2005-2015. In the PWB group, the patients were discharged to a rehabilitation center, where they were treated according to the PWB protocol. Since 2003 PWB was gradually implemented and became standard care in our rehabilitation center from 2005. The fracture aftercare process starts by assessing the patient's profile. Next, the generic and patient-specific treatment goals are identified, which, when combined, lead to the aftercare treatment aims. These aftercare treatment aims are then contrasted to the patient's profile descriptors, which, together with potential predictors of surgically treated fracture aftercare outcome, may give insight into a) the feasibility of the aftercare treatment aims; b) the estimated time frame in which the aftercare treatment aims may be reached; and c) the intensity/dosage/weight bearing needed to achieve the aftercare treatment aims. The increase in weight bearing is not based on a fixed percentage per week: weight bearing is gradually increased, based on the patient's clinical presentation and with special attention to the quality of gait. Other key elements include body awareness and safe patient handling and moving algorithms, which are also considered to be key factors for successful treatment. The program involves multidisciplinary cooperation with surgeons, rehabilitation physicians and physical therapists, which is considered paramount to safely use the PWB protocol.

The patients included in the protocol suffered from two or more fractures (upper and lower extremity fractures) and therefore needed more aftercare. The patients in the RWB group were discharged to their own home. They received passive exercise to maintain the muscles and the knee joint supported by a physical therapist, as prescribed by the surgeon.

All data in the study were collected from the electronic medical records by one researcher. Demographics of patients included age, gender and the presence of other fractures at the same time.

Primary outcome measures included the patient-reported questionnaire after at least 1-year follow up; 1) Quality of life measured with the Short Form 12 (SF-12).²⁰ The SF-12 consists of 12 items that assess 8 dimensions of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The SF-12 measures various aspects of physical and mental health from which physical and mental summary scores can be calculated. 2) The intensity of pain measured with the VAS scale, (0 is no pain and 10 is worst pain).²¹

Time from surgery till full weight bearing and the total number and type of postoperative complications were collected from the electronic medical records. A postoperative complication was defined as a composite end-point comprising any complication, related to the fracture, that occurred during the aftercare regimen, these were recorded as either present or not present, along with the type of complications.

The medical ethics committee of Zuyderland Medical Center, Heerlen, the Netherlands approved this study and informed consent was given by all patients.

Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics, Version 23.0, Armonk, New York. Descriptive statistics were used to describe the demographic data and baseline characteristics of the entire population. Independent samples t-tests were used for normally distributed continuous data and chi-squared tests for categorical variables. Results are presented as either mean \pm standard deviation (SD) or as frequencies and percentages. In case of non-parametric data the median with the interquartile range (IQR) are described. Binary logistic regression was performed to assess independent predictors of late full weight bearing (>12 weeks) throughout both PWB and RWB groups. The level of statistical significance was set at $\alpha=0.05$.

Results

Baseline characteristics

This cohort study included 91 patients, 31 of whom were in the PWB group and 60 in the RWB group. Characteristics of patients in the PWB group and RWB group are presented in Table 6.1. Patients in the PWB group were significantly more likely to have a more complex fracture type (Schatzker fracture type (IV-VI)²²) ($p=0.04$) and more concomitant fractures than those in the RWB group ($p<0.01$). No differences in age or gender were found between the two groups. Furthermore, no differences were found in surgical procedures between the two groups.

Table 6.1 Baseline characteristics of the PWB and RWB groups.

	PWB (N=31)	RWB (N=60)	Total (N=91)	p
Female	12 (38.7%)	27 (45.0%)	39 (42.9%)	0.66
Mean age (SD), years	50.4 (12.6)	50.9 (12.4)	50.8 (12.4)	0.86
≥ 2 fractures	26 (83.9%)	5 (8.3%)	31 (34.1%)	<0.01
Schatzker types:				
Type I - III	7 (22.6%)	27 (45.0%)	34 (37.4%)	0.04
Type IV- VI	24 (77.4%)	33 (55.0%)	57 (62.6%)	

Abbreviation: SD, standard deviation.

Patient-reported quality of life and pain

The overall response rate of the patient-reported questionnaire SF-12 and VAS scale was 72.5% (i.e. 66/91). No significant difference was found in response rate between the PWB group (80.6%) and RWB (68.3%) group ($p=0.32$). The time between surgery and the moment at which the questionnaires administered was significantly higher in the RWB group than in the PWB group: 7.6 (3.2) years versus 4.6 (2.4) years ($p<0.01$). No significant between-group differences were found in either quality of life measured with the SF-12 or the pain measured with the VAS scale (Table 6.2).

Table 6.2 Functional outcome measurements in the PWB and RWB groups.

	PWB (N=25)	RWB (N=41)	Total (N=66)	p
Mean SF-12 (quality of life) (SD)	58.0 (20.7)	68.8 (23.1)	64.7 (22.7)	0.06
Mean VAS scale (pain) (SD)	3.6 (2.2)	2.8 (2.7)	3.1 (2.5)	0.24

Abbreviation: SD, standard deviation.

From the total population 38.5% of the patients (N=35) reached full weight bearing within 12 weeks. The number of patients who reached full weight bearing within 12 weeks was significantly higher in the PWB group than in the RWB group: 58.1% versus 28.3% ($p<0.01$). Time from surgery to ascertainment of full weight bearing was significantly shorter in the PWB group than in the RWB group: 14.7 (11.6) weeks versus 20.7 (11.5) weeks ($p=0.02$) (Table 6.3). Binary logistic regression analysis revealed that, irrespective of PWB or RWB, Schatzker type and multiple fractures ($p<0.05$) were independent predictors of late full weight bearing (>12 weeks). No significant differences were found in time from surgery to full weight bearing between the specific fracture types (Schatzker type I-III versus Schatzker type IV-VI) ($p=0.10$) in the PWB group (Table 6.4).

Table 6.3 Time to full weight bearing in the PWB and RWB groups.

	PWB (N=31)	RWB (N=60)	Total (N=91)	p
Within 12 weeks	18 (58.1%)	17 (28.3%)	35 (38.5%)	<0.01
Mean time to full weight bearing (SD), in weeks	14.7 (11.6)	20.7 (11.5)	18.6 (11.9)	0.02

Abbreviation: SD, standard deviation.

Table 6.4 Time to full weight bearing for specific fracture types in the PWB group.

	Schatzker Type I - III (N=7)	Schatzker Type IV - VI (N=24)	Total Type I - VI (N=31)	p
Within 12 weeks	6 (85.7%)	12 (50.0%)	18 (58.1%)	0.10
Mean time to full weight bearing (SD), in weeks	8.3 (5.1)	16.5 (12.4)	14.7 (11.6)	0.10

Abbreviation: SD, standard deviation.

Patient outcome

No significant differences were found in the incidence of postoperative complications between the PWB group and the RWB group, values of which were 6.5% (N=2) versus 10.0% (N=6) respectively. In the PWB group. The complications in the PWB group consisted of N=1 non-union and N=1 superficial wound infection. It should be noted, however, that both patients started full weight bearing after the postoperative complication. The complications in the RWB group consisted of N=3 non-unions, N=2 superficial wound infections and N=1 deep infection. Furthermore, no significant differences between the PWB group and RWB group were found regarding either the postoperative removal of osteosynthesis material or the number of total knee prostheses (Table 6.5).

Table 6.5 Patient outcome measurements in the PWB and RWB groups.

	PWB (N=31)	RWB (N=60)	Total (N=91)	p
Total postoperative complications	2 (6.5%)	6 (10.0%)	8 (8.8%)	0.58
Postoperative ROSM	7 (22.6%)	24 (40.0%)	31 (34.1%)	0.10
Postoperative TKP	5 (16.1%)	5 (8.3%)	10 (11.0%)	0.27

Discussion

This retrospective cohort study found that the use of a PWB protocol for patients with a surgically treated tibial plateau fracture was associated with reduced time to full weight bearing, while similar quality of life, pain and postoperative complication rates were found, compared to RWB. Furthermore, no significant differences were found in rates of postoperative removal of osteosynthesis material or the need for total knee prostheses after tibial plateau fractures.

In our study 28.3% of patients in the RWB were already bearing full weight within 12 weeks, highlighting the contrast to the standard protocol of 12 weeks non-weight bearing. The patients in the PWB group were already bearing full weight 6 weeks earlier than the RWB group. In addition, earlier studies reported that one third of the patients do not (fully) comply to a non- or limited weight bearing regimen.^{4,5} A number of studies found patients to exceed the prescribed amount of partial weight bearing even when self-reported compliance was high.²³ Despite the willingness to comply, patients often do not follow the restrictions in weight bearing and advance their weight bearing as fracture healing progresses.

During normal daily activities the knee joint experiences forces between 220% and 350% of a person's body weight. As even a 3-mm step-off in the tibial plateau can increase the cartilage contact stresses by 75%, concerns are raised that loss of reduction could lead to worse patient outcomes, even in case of non-weight bearing.²⁴ On the other hand, it is often stated that early weight bearing does not pose an undue risk of complications or worse patient outcomes compared to a non-weight bearing protocol, as reported in a recent randomized controlled trial dealing with fractures of the ankle joint.²⁵ These two statements are contradictory and require further elaboration. Our study adds evidence in favor of regimens with earlier than standard postoperative weight bearing protocols and shows that there is no significant difference in quality of life, pain or complications compared to RWB.

One of the key objections against early weight bearing is the possibility of fracture displacement.²⁶ In one radiostereometric study at one year after early weight bearing of fractures of the tibial plateau, the mean craniocaudal migration of the fracture fragments was -0.34 mm (-1.64 to 1.51).²⁷ This case series has shown that, in the Schatzker type II fractures investigated, internal fixation with subchondral screws and a buttress plate provided adequate stability to allow immediate post-operative partial weight-bearing, without harmful consequences.

Longer term outcomes have as well been described in the literature, with more favorable results for PWB. In a prospective, multicenter randomized trial involving bicondylar tibial plateau fractures, a group of 43 patients underwent fixation with external ring fixation and were permitted to bear full weight, while a group of 40 patients underwent open reduction and internal fixation with restricted weight bearing.⁸ At a minimum 2-year follow-up, there was no difference in reoperations, articular incongruity, or development of radiographic signs of osteoarthritis between the two groups. In line with this study, our study found that there were no significant differences in pain or reoperations (removal of osteosynthesis material or implants of total knee prostheses). Interestingly, removal of osteosynthesis material in the PWB group was lower than in RWB group, i.e. 22.6% versus 40.0%, respectively.

According to recent literature, a composite postoperative complication rate of up to 27% has been reported in tibial plateau fractures.⁷⁻¹⁴ Comparing our complication data with data published in recent literature, we found decreased rates of postoperative complication in tibial plateau fractures treated by means of a PWB protocol, despite the fact that more severe fractures were found in our PWB population. The latter could be an explanation for the fact that the other 41.9% of the PWB population did not reach full weight bearing within 12 weeks, which might be due to a high comorbidity rate of our PWB population. Nevertheless, the average time to full weight bearing was significantly lower in the PWB group than the RWB group.

Over and under-loading may lead to prolonged and complicated recovery. A certain minimum level of loading is required to elicit micro-movements between adjacent bony fracture components, stimulating biological processes that enhance fracture consolidation and minimizing effects of immobilization.^{28,29} To optimize recovery with the lowest number of complications we want to set out a treatment that is near to the upper boundary of the therapeutic bandwidth regarding weight bearing, yet safe enough to avoid complications regarding overloading.

Our study, the first study comparing PWB with RWB, adds evidence in support of the use of PWB in patients with surgically treated tibial plateau fractures. However, limitations in our study include the retrospective nature of the study and, due to this retrospection, not taking into account surgeon-oriented functional outcome scores (e.g. knee function) or generic patient satisfaction scores. Furthermore, no radiological controls have been done to investigate the alignment of the fractures. Another limitation of the study is the lack of monitoring patient compliance. To mitigate these limitations, we have started a prospective cohort study in patients with fractures of the lower extremities.³⁰

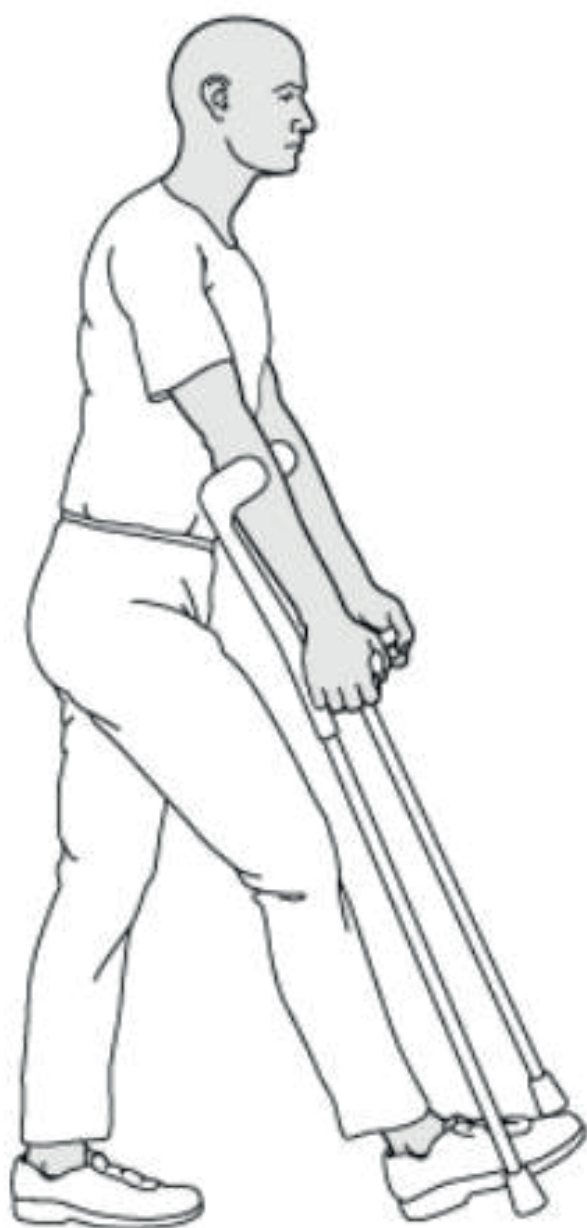
Conclusion

This retrospective cohort study shows that permissive weight bearing after surgically treated tibial plateau fractures is safe and is related to a significant reduced time to full weight bearing with no significant differences in patient-reported quality of life and pain or complication rates.

References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. *Injury*. 2006;37(8):691-7.
2. Ruedi TP, Buckley RE, Moran CG. *AO principles of fracture management*, 2nd edn. Thieme, New York. 2007;832
3. van der Vusse M, Kalmet PHS, Bastiaenen CHG et al. Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands. *Arch Orthop Trauma Surg*. 2017;137(8):1071-5.
4. Hurkmans HL, Bussmann BJ, Selles RW et al. The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy: Long-term vertical force measurements inside and outside the hospital. *Arch Phys Med Rehab*. 2007;88:200-6.
5. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics*. 2012;35:e31-7.
6. Kammerlander C, Pfeufer D, Lisitano LA et al. Inability of Older Adult Patients with Hip Fracture to Maintain Postoperative Weight-Bearing Restrictions. *J Bone Joint Surg Am*. 2018;100:936-41.
7. Basques BA, Webb ML, Bohl DD et al. Adverse events, length of stay, and readmission after surgery for tibial plateau fractures. *J Orthop Trauma*. 2015;29(3):e121-6.
8. Canadian Orthopaedic Trauma Society. Open reduction and internal fixation compared with circular fixator application for bicondylar tibial plateau fractures. Results of a multicenter, prospective, randomized clinical trial. *J Bone Joint Surg Am*. 2006;88(12):2613-23.
9. Choo KJ, Morshed S. Postoperative complications after repair of tibial plateau fractures. *J Knee Surg*. 2014;27(1):11-9.
10. Cuellar-Avaroma A, King-Martinez AC, Hernandez-Salgado A, Torres-Gonzalez R. [Complications in complex fractures of the tibial plateau and associated factors]. *Cir Cir*. 2006;74(5):351-7.
11. Luo CF, Sun H, Zhang B, Zeng BF. Three-column fixation for complex tibial plateau fractures. *J Orthop Trauma*. 2010;24(11):683-92.
12. Prasad GT, Kumar TS, Kumar RK et al. Functional outcome of Schatzker type V and VI tibial plateau fractures treated with dual plates. *Indian J Orthop*. 2013;47(2):188-94.
13. Qiu WJ, Zhan Y, Sun H et al. A posterior reversed L-shaped approach for the tibial plateau fractures-A prospective study of complications (95 cases). *Injury*. 2015;46(8):1613-8.
14. Ruffolo MR, Gettys GF, Montijo HE et al. Complications of high-energy bicondylar tibial plateau fractures treated with dual plating through 2 incisions. *Journal of Orthopaedic Trauma*. 2015;29(2):85-90.
15. Haller JM, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthop Clin North Am*. 2013;44(4):509-19.
16. Kubiak EN, Beebe MJ, North K et al. Early weight bearing after lower extremity fractures in adults. *J Am Acad Orthop Surg*. 2013;21(12):727-38.
17. Bailon-Plaza A, van der Meulen MC. Beneficial effects of moderate, early loading and adverse effects of delayed or excessive loading on bone healing. *J Biomech*. 2003;36(8):1069-77.
18. Claes LE, Heigele CA, Neidlinger-Wilke C et al. Effects of mechanical factors on the fracture healing process. *Clin Orthop Relat Res*. 1998;(355 Suppl):S132-47.
19. Gardner MJ, van der Meulen MC, Demetrakopoulos D et al. In vivo cyclic axial compression affects bone healing in the mouse tibia. *J Orthop Res*. 2006;24(8):1679-86.
20. Ware JE, Kosinski M, Keller SD. *How to score the SF-12 physical and mental health summaries: a user's manual*. Boston: New England Medical Centre. 1995.
21. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. *Psychol Med*. 1998;18:1007-19.
22. Schatzker J, Mcbroom R, Bruce D. The tibial plateau fracture: the Toronto experience 1968-1975. *Clin Orthop Relat Res*. 1979;138:94-104.
23. Warren CG, Lehmann JF. Training procedures and biofeedback methods to achieve controlled partial weight bearing: an assessment. *Arch Phys Med Rehabil*. 1975;56(10):449-55.
24. Thomas G, Whalley H, Modi C. Early mobilization of operatively fixed ankle fractures: a systematic review. *Foot Ankle Int*. 2009;30(7):666-74.

25. Swart E, Bezhani H, Greisberg J et al. How long should patients be kept non-weight bearing after ankle fracture fixation? A survey of OTA and AOFAS members. *Injury*. 2015;46:1127-30.
26. Black JD, Bhavikatti M, Al-Hadithy N et al. Early weight-bearing in operatively fixed ankle fractures: a systematic review. *Foot*. 2013;23(2-3):78-85.
27. Solomon LB, Callary SA, Stevenson AW et al. Weight-bearing-induced displacement and migration over time of fracture fragments following split depression fractures of the lateral tibial plateau: a case series with radiostereometric analysis. *J Bone Joint Surg Br*. 2011;93(6):817-23.
28. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. *Injury*. 2008;39(7):725-7.
29. de Morree JJ. Dynamics of human connective tissue [Dynamiek van het menselijk bindweefsel]. Houten, the Netherlands: Bohn Stafleu van Loghum. 2009.
30. Kalmet PHS, Meys G, V Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg*. 2018;18(1):8.



Chapter 7

Effectiveness of permissive weight bearing in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities: a prospective comparative multicenter cohort study

Kalmet PHS
Maduro CV
Meys G
van Horn YY
Hustinx P
van Vugt R
Janzing H
van der Veen A
Jaspars C
Sintenie JB
Blokhuys TJ
Evers SMAA
Seelen HAM
Brink PRG
Poeze M
Submitted

Abstract

Background

The aim of the present study was to investigate the effectiveness of a novel approach involving permissive weight bearing (PWB) in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. This paper reports on patients' self-perceived outcome levels regarding activities of daily living (ADL), quality of life (QoL), pain and weight bearing compliance, in comparison to restricted weight bearing (RWB), over a 26-week post-surgery follow-up period.

Methods

This prospective comparative multicenter cohort study included surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. Primary outcome: ADL. Secondary outcomes: QoL, pain, compliance as measured with insoles, and postoperative complications. Measurements were performed at 2, 6, 12 and 26 weeks post-surgery.

Results

This study included 106 trauma patients (N=53 in both the PWB and RWB groups). Significantly better ADL and QoL were found in the PWB group compared to the RWB group at 2, 6, 12 and 26 weeks post-surgery. There were no significant differences in postoperative complication rates between the PWB and RWB groups.

Conclusion

PWB is effective and is associated with a significantly reduced time to full weight bearing, and a significantly better outcome regarding ADL and QoL compared to patients who followed RWB regimen. Moreover, no significant differences in complication rates were found between the PWB and RWB groups.

Introduction

The recommendations for aftercare in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities are still more or less the same as they were during the last 60 years, without any source of evidence being given for the advice of restricted weight bearing.¹ In view of this lack of evidence, many orthopedic and trauma surgeons tend to advise conservatively with regard to postoperative management and hold on to the prevailing dogmas, i.e. non-weight bearing or restricted weight bearing.²

The current recommendations regarding postoperative management in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities is either non-weight bearing or restricted weight bearing for 6-12 weeks, followed by partial weight bearing with a 25% increase in weight every week.^{1,3}

There is no consensus from the surgeons in the current postoperative management.⁴ Moreover, almost 90% of the surgeons deviate from the current postoperative management protocols because of e.g. type of fracture, (un-) certainty of fixation, clinical experience or gut feeling.⁴ Furthermore, while instructions on rehabilitation provided to patients may be clear, patients' compliance with a non-weight bearing or restricted weight bearing regimen is poor, so neither surgeons nor patients follow the instructions regarding the postoperative management regimen.^{5,6}

The postoperative management of surgically treated peri- and intra-articular fractures of the lower extremities is very important in view of the impact on the patient's functional outcome. Recent literature has reported composite postoperative complication rates of up to 37%, with an average of 10–20% for patients with lower extremity fractures.⁷⁻¹¹ In addition, several studies indicate that the postoperative management, i.e. early or permissive weight bearing, increases the postoperative complications rates.^{3,4}

Several biomechanical, animal and clinical studies have found early or permissive weight bearing to be beneficial.^{2,3,12-15} However, very few clinical studies are available that compared permissive weight bearing (PWB) with restricted weight bearing (RWB) in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. Furthermore, despite the generally accepted value of the use of patient-specific outcome measures, no data is available offering insights into patients' self-perceived outcome levels (e.g. regarding activities of daily living (ADL), quality of life or pain) in either PWB or RWB.

The aim of the present study was therefore to investigate the effectiveness of PWB in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities, reporting on patients' self-perceived outcome levels regarding ADL, quality of life, pain, weight bearing or patients' compliance and postoperative complications, in comparison to RWB, over a 26-week post-surgery follow-up period.

Methods

Study design and participants

This prospective comparative multicenter cohort study included surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. Subjects were consecutively recruited from six hospitals in the Netherlands between October 2017 and September 2018. The allocation of the patients to the intervention or control group depended on the regimen adhered to by the hospital in which the patients were surgically treated. During the conceptualization of this study design, an important choice had to be made concerning randomization. Patient randomization was not considered feasible because of the nature of the two different interventions. Implementation of these different protocols includes patient instructions as well as physical therapy guidance and nursing staff participation. A mix of treatment protocols on a single ward was therefore considered suboptimal because of information bias. However, this meant we had to take into account that not randomizing the study could introduce observer bias, which may be a study limitation. Patients from two hospitals underwent the PWB protocol² as aftercare rehabilitation treatment, while the others followed the RWB¹ protocol.

Surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities (i.e. pelvic fractures, acetabular fractures, distal femur fractures, tibial plateau fractures, pilon fractures, calcaneal fractures and talar fractures) were eligible for inclusion if they were aged 18 years or over. Patients with pathological fractures, shaft fractures treated with intra-medullary nailing, hip fractures treated with prosthesis, or fractures treated with external fixation, and patients with amputations in the area of the lower extremity, were excluded. Patients with cognitive dysfunction to follow instructions or due to the consequences of severe neurotrauma or due to concomitant or mental illness were also excluded.¹⁶

Protocols

The PWB treatment involves a gradual progression in functional activities guided by patients' subjective experience (pain and confidence to bear weight) and by objective clinical symptoms of the patients occurring during the process of rehabilitation,

evaluated by the physical therapist during every outpatient physiotherapy session. Clinical symptoms include the evolution of signs of inflammation, neuro-vascular status, weight-bearing tolerance, changes in the alignment of the affected side of the body, and the quality and function of the soft tissue and the joints involved. This progression in patients' functional activities is determined from the quality of performance of a functional activity. The progress in therapy is not determined by any predetermined or fixed degree of loading of the affected side in kg or in percentage of body weight, as this has proved to be difficult to adhere to. This process enables patients to carry out the activities with normal/optimal motor skills as soon as possible. The approach is guided by the quality of performance and the safety of the activity (e.g. preventing stumbling). The next stage of the treatment is started when the gait pattern associated with the current stage of the treatment is optimally executed, and can be performed by the patient safely and independently.²

In the RWB group, the patients underwent a non-weight bearing regimen for 6-12 weeks followed by partial weight bearing with a 25% increase in weight loading every week according to the existing (AO) guidelines.¹

Outcome measures and co-variables

The patients' self-perceived outcome levels, questionnaires related to the activities of daily living (ADL) were assessed as primary outcome measure. ADL was measured with the Lower Extremity Functional Scale (LEFS). The LEFS consists of 20 questions about a person's ability to perform daily tasks. The score for each question ranges from 0 (extreme difficulty in performing the activity) to 4 (good performance of activity), maximizing the score at 80 points. The lower the score, the greater the disability.¹⁷

The other patients' self-perceived outcome levels were assessed as secondary outcome measures, using questionnaires related to the quality of life and pain score. The quality of life was measured with the Short Form-12 (SF-12) questionnaire. The SF-12 consists of 12 items that assess 8 dimensions of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The SF-12 measures various aspects of physical and mental health from which a physical composite score (PCS) and a mental composite score (MCS) can be calculated, ranging from 0 to 100.¹⁸ The intensity of pain was measured with the Numeric Rating Scale (NRS; 0 indicating no pain and 10 worst pain).¹⁹ All patients' self-perceived outcome levels were obtained at the follow-up time-points of 2, 6, 12 and 26 weeks post-surgery. The other secondary outcome measures were the rehabilitation outcome (i.e. outpatient physiotherapy, time to full weight bearing, completion of rehabilitation within 26 weeks), complications during a 26-week post-surgery follow-up and the progression of weight bearing during the first 12 weeks of rehabilitation.

Postoperative complications, i.e. superficial wound infections, deep wound infections, non-unions and secondary dislocations, or other additional adverse situations that required medical intervention, were recorded as either present or non-present, along with the type of complication. Removal of implants was only performed in case of functional complaints.

All patients' compliance were monitored for 3 months after surgery with the OpenGo insole (Moticon GmbH, Munich, Germany).²⁰ The insole incorporates 13 capacitive pressure sensors and a 3D accelerometer, measuring peak pressures (in Newton) and mean weight bearing (in Newton). It operates completely wireless. Data is stored on a flash drive. The insole can be placed in any shoe and shoes can be changed at random during the study due to an automated zeroing system.²⁰

Baseline characteristics, recorded at admission, included age at time of fracture, sex, ASA (American Society of Anesthesiologists) classification (type 1–6),²¹ Charlson comorbidity score (classifying prognostic comorbidity, a higher score correlating with additional comorbidities),²² type of fracture and in-hospital length of stay (in days).

Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics (Version 25.0, Armonk, NY). Descriptive statistics were used to describe the demographic data and baseline characteristics for the entire study population. Independent samples t-tests were used for normally distributed continuous data, and chi-squared tests for categorical variables. In the case of non-parametric data, the median with the interquartile range was calculated. Furthermore, a linear mixed model was used to identify any differences among the outcome measures over time. This analysis ensured that both random and cluster effects, such as treatment in different hospitals, and fixed effects, such as ASA classification, could be considered and corrected for. Results are presented as either mean (standard deviation) or frequencies and percentages. The level of statistical significance was set at $\alpha=0.05$. The data was analyzed blinded by the researchers.

Results

Baseline characteristics

A total of 106 patients were included in this cohort study: N=53 in each of the PWB and RWB groups (Figure 7.1). As the assumption for normality was violated, non-parametric tests were used, and established that the PWB group patients had comparable ASA score ($p=0.14$) and fewer comorbidities, as measured with the Charlson score, ($p=0.03$) compared to those in the RWB group. No significant differences in sex, age, type of

fracture, number of surgical interventions during primary admission or in-hospital length of stay were found between the groups. Characteristics of patients in the PWB and RWB groups are summarized in Table 7.1.

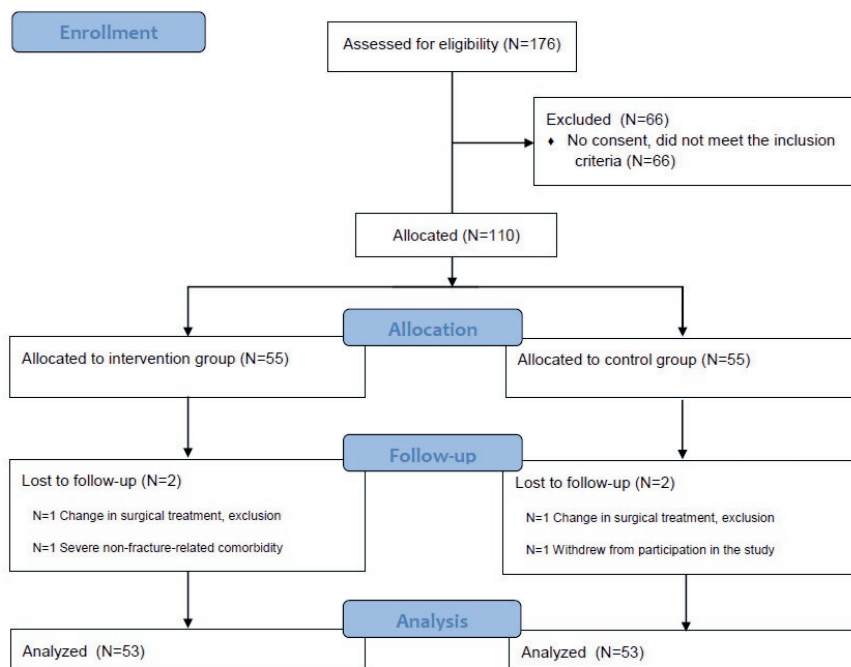


Figure 7.1 CONSORT Flowchart of study patients.

Table 7.1 Baseline characteristics and in-hospital outcome of the PWB and RWB groups.

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Female, N	27 (50.9%)	27 (50.9%)	54 (50.9%)	1.00
Median age (IQR), years	55.0 (38.5-65.0)	60.0 (47.0-67.0)	58.0 (43.5-66.3)	0.27
ASA, N				0.14
I, II	49 (92.5%)	44 (83.0%)	93 (87.7%)	
> II	4 (7.5%)	9 (17%)	13 (12.3%)	
Median Charlson score (IQR)	1 (0-3)	2 (1-3)	2 (0-3)	0.03
Fracture type, N:				0.18
- Pelvic	7 (13.2%)	1 (1.9%)	8 (7.5%)	
- Acetabular	5 (9.4%)	3 (5.7%)	8 (7.5%)	
- Tibial plateau	16 (30.2%)	28 (52.8%)	44 (41.5%)	
- Pilon	17 (32.1%)	12 (22.6%)	29 (27.4%)	
- Calcaneal	8 (15.1%)	9 (17.0%)	17 (16%)	
In-hospital outcome:				
Two or more procedures (%)	9 (17.0)	8 (15.1)	17 (16.0)	0.57
Median length of stay (IQR), in days	7.0 (2.0-15.5)	5.0 (2.0-11.5)	6.0 (2.0-14.0)	0.24

Abbreviations: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; ASA, American Society of Anesthesiologists; IQR, interquartile range.

Primary outcome measures

After a 26 week post-surgery follow-up, the overall response rate for the patient-specific outcome measures at all measurement points was 99.8% (N=1 patient refused to fill out the patient self-perceived outcome questionnaires at week 26). ADL as measured with the LEFS, and quality of life as measured with the SF-12, were both significantly better in the PWB group compared to the RWB group ($p<0.01$) (Appendix 7.1). There were no differences in pain score between the PWB and RWB groups (Appendix 7.2). The patient self-perceived outcome levels regarding ADL and quality of life in the PWB and RWB groups are summarized in Figures 7.2 and 7.3.

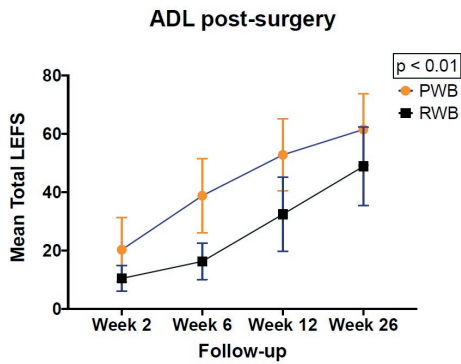


Figure 7.2 Unadjusted patient self-perceived activities of daily living during a 26-week post-surgery follow-up. ADL, Activities of Daily Living; LEFS, Lower Extremity Functional Scale; PWB, permissive weight bearing; RWB, restricted weight bearing.

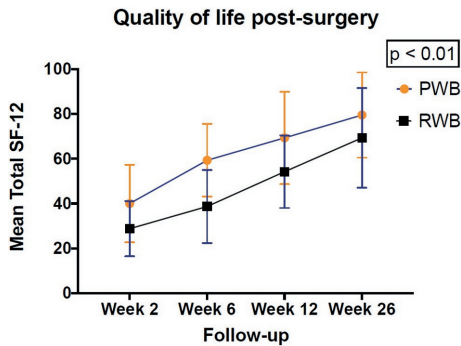


Figure 7.3 Unadjusted patient self-perceived quality of life during a 26-week post-surgery follow-up. PWB, permissive weight bearing; RWB, restricted weight bearing.

Rehabilitation and postoperative outcome

Of the total patient population, 77.4% (N=82) achieved full weight bearing within 12 weeks. The number of patients who achieved this was significantly higher in the PWB group than in the RWB group: 98.1% versus 56.6% ($p<0.01$). The median time from surgery to ascertainment of full weight bearing was significantly shorter in the PWB group than in the RWB group: 4.0 (2.1) weeks versus 12.2 (4.2) weeks ($p<0.01$). The incidence of postoperative complications in the total study population was 16.0%, with no significant differences between the PWB group and the RWB group (11.3% [N=6] versus 20.8% [N=11], respectively ($p=0.19$), see Table 7.2.

Table 7.2 Rehabilitation outcome and postoperative complications in the PWB and RWB groups.

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Prescribed rehabilitation aftercare (%):				
PWB	53 (100)	0 (0)	53 (50)	
6 weeks RWB	0 (0)	36 (67.9)	36 (34.0)	
8 weeks RWB	0 (0)	3 (5.7)	3 (2.8)	
12 weeks RWB	0 (0)	14 (26.4)	14 (13.2)	
Rehabilitation outcome:				
Median OPD (IQR), in hours	25 (13.0-46.8)	41 (28.5-57.5)	33 (18.5-52.0)	0.01
FWB within 12 weeks (%), N	52 (98.1)	30 (56.6)	82 (77.4)	<0.01
Median time to FWB (IQR), in weeks	4.0 (2.0-7.0)	13.0 (9.0-15.0)	8.0 (4.0-13.0)	<0.01
N who completed rehabilitation within 26 weeks (%)	30 (65.2)	16 (34.8)	46 (43.4)	<0.01
Total post-operative complications (%)				
Non-unions	6 (11.3)	11 (20.8)	17 (16.0)	0.19
Secondary dislocations	0 (0.0)	1 (1.9)	1 (0.9)	
Superficial wound infections	1 (1.9)	2 (3.8)	3 (2.8)	
Deep wound infections	3 (5.7)	6 (11.3)	9 (8.5)	
Removal of osteosynthesis material	1 (1.9)	1 (1.9)	2 (1.9)	

Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; IQR, interquartile range; OPD, outpatient physiotherapy duration; FWB, full weight bearing.

Weight bearing compliance

The mean weight bearing and peak loading were not significantly different between the subjects who followed the PWB or RWB regimens, see Figures 7.4 and 7.5.

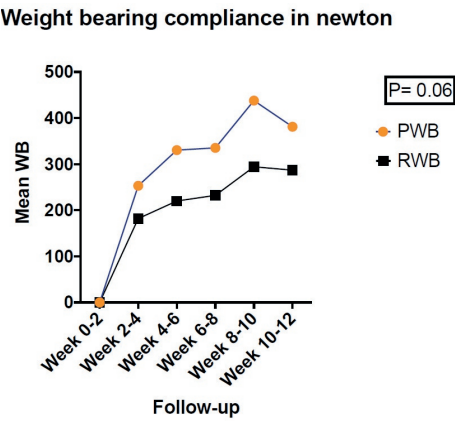


Figure 7.4 Mean weight bearing compliance during a 26-week post-surgery follow-up. Abbreviation: PWB, Permissive weight bearing; RWB, Restricted weight bearing; N, number of subjects; SD, standard deviation; WB, Weight bearing in newton on affected leg.

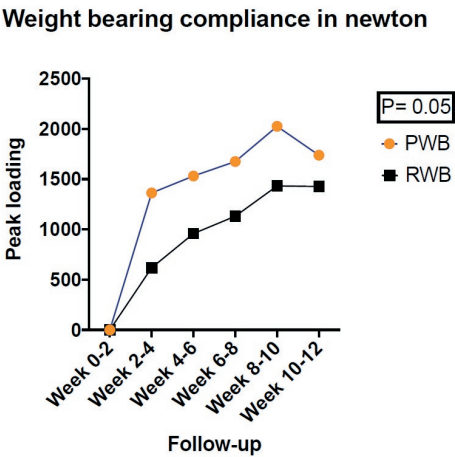


Figure 7.5 Weight bearing compliance expressed in peak loading during a 26-week post-surgery follow-up. Abbreviations: PWB, Permissive weight bearing; RWB, Restricted weight bearing; N, number of subjects; SD, standard deviation; Peak loading, Peak loading in newton on affected leg.

Discussion

The aim of this study was to investigate the effectiveness of a novel approach involving permissive weight bearing (PWB) in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. The PWB regimen led to the patients

being able to bear full weight on their affected leg much sooner, with a better ADL and quality of life, compared to those who followed the usual RWB regimen. No significant differences between the two treatment regimens were found in either postoperative complication rates or pain levels.

Patients' self-perceived outcome levels were significantly better among patients who followed the PWB protocol than among those who followed the RWB protocol. This study found a general improvement in ADL (LEFS) and quality of life (SF-12) for both groups during the 26-week rehabilitation period. In our total population, the mean LEFS 26 weeks post-surgery was 55.2 (14.3). This is in line with earlier studies, which found similar levels of ADL in trauma patients after surgery of the lower extremities.²³⁻²⁵ The mean quality of life for the total population in our study was also in the same range as that reported by other studies.^{26,27}

Despite the early PWB regimen, the recorded pain levels during the 26-week rehabilitation period were higher in the RWB group than in the PWB group, which could be due to the consequences of immobilization.²

In our study 56.6% of the patients in the RWB group were already bearing full weight within 12 weeks, in contrast to the standard protocol of 12 weeks non-weight-bearing or partial weight bearing.¹ Earlier studies also reported that one-third of patients (due to e.g. cognitive impairment in older patients to follow instructions) did not comply with a non-weight-bearing or restricted weight bearing regime.^{5,6} Despite the willingness to comply, patients often do not follow the weight-bearing restrictions and increase their weight bearing as fracture healing progresses.⁶ This is also in line with our data on weight bearing, as measured with the Moticon insoles. These measurements showed that there was no significant difference in mean weight bearing between the RWB and PWB groups. The difference in peak loading was nearly significant between the RWB group and PWB group: $p=0.05$. The patients in the PWB group were bearing full weight 9 weeks earlier than those in the RWB group. The effort to bear weight earlier was not at the expense of longer duration of outpatient physiotherapy. In fact, the RWB group required significantly longer outpatient physiotherapy than the PWB group, viz. 41 versus 25 hours, respectively. Furthermore, significantly more patients in the PWB group completed the rehabilitation within 26 weeks compared to the RWB group, viz. 65.2% versus 34.8%.

Our study found that there was no significant difference in postoperative complications between the PWB group and the RWB group. One of the key objections often raised against early weight bearing is the possibility of fracture displacement.²⁸ On the other hand, it has often been stated that early weight bearing does not entail an undue risk of postoperative complications.^{2,3,12,13,29} These two views are contradictory,

and our study provides evidence in favor of regimes with early weight bearing instead of the standard non-weight-bearing protocols. According to recent literature, a composite postoperative complications rate of up to 27% has been found in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities.⁷⁻¹¹ Comparison of our complication rates with data published in recent literature shows that we found lower rates of postoperative complication in these patients when they were treated with the PWB regimen.

Over- and under-loading may lead to prolonged and complicated recovery.² A certain minimum level of loading is required to elicit micro-movements between adjacent bony fracture components, stimulating biological processes that are converted into cellular signals initiating bone remodeling.^{27,30} This process is described in the literature as the mechanotransduction in bone. Mechanotransduction is continuously present and enables the bone to resist the mechanical impacts caused by daily activities.³⁰ To optimize recovery with the lowest number of complications and better patients' self-perceived outcome levels, one should apply a treatment that approaches the upper limit of the therapeutic bandwidth regarding weight bearing, yet is safe enough to avoid complications due to overloading. This is the case with the PWB protocol.²

Our study, the first large-scale prospective multicenter cohort study comparing PWB with RWB, adds evidence in support of the use of PWB in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. This means that our study contests the paradigm of the current RWB guidelines, which have remained unchanged for 60 years. The time has now come to renew the current guidelines in accordance with the most recent evidence.

When interpreting our data, some limitations have to be considered. Due to practical reasons, this study featured a non-randomized groups design. However, patients were included to the PWB and RWB groups consecutively to avoid selection bias. There were differences regarding the patients' comorbidities and the different hospitals in which the patients were treated. Our statistical analyses took these issues into consideration, thus correcting the presented results for the confounding influence that these factors may have had on the study results. Surgeon-oriented functional outcome scores (e.g., the function of a knee or ankle joint) were not taken into account. No radiological assessment was used to assess the alignment of the fractures. Further data are needed on the cost-effectiveness, radiological assessment, and long-term patient-reported outcome of the PWB strategy.

Conclusion

This prospective, comparative, multicenter study shows that PWB in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities is effective and is associated with a significant reduction in time to full weight bearing and significantly better outcomes in terms of ADL and quality of life compared to the RWB regime, with a similar complication rate. This PWB protocol contests the paradigm of the current RWB guidelines, which have remained unchanged for over 60 years.

References

1. Ruedi TP, Buckley RE, Moran CG. AO principles of fracture management. Third edition. New York. Thieme. 2018.
2. Meys G, Kalmet PHS, Sanduleanu S et al. A protocol for permissive weight-bearing during allied health therapy in surgically treated fractures of the pelvis and lower extremities. *J Rehabil Med.* 2019;51: 290-7.
3. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthop Clin N Am.* 2013;44:509–19.
4. van der Vusse M, Kalmet PHS, Bastiaenen CHG et al. Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands. *Arch Orthop Trauma Surg.* 2017;137:1071-75.
5. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics.* 2012;35:e31–7.
6. Raaben M, Holtslag HR, Leenen LPH et al. Real-time visual biofeedback during weight bearing improves therapy compliance in patients following lower extremity fractures. *Gait Posture.* 2018;59:206-10.
7. Choo KJ, Morshed S. Postoperative complications after repair of tibial plateau fractures. *J Knee Surg.* 2014;27:11–9.
8. Yu X, Pang QJ, Chen L et al. Postoperative complications after closed calcaneus fracture treated by open reduction and internal fixation: a review. *J Int Med Res.* 2013;42:17–25.
9. Halvorson JJ, Winter SB, Teasdall RD, Scott AT. Talar neck fractures: a systematic review of the literature. *J Foot Ankle Surg.* 2013;52:56–61.
10. Schwabe P, Wichlas F, Druschel C et al. Complications after osteosynthetic treatment of acetabular fractures. *Orthopäde.* 2014;43:24–34.
11. Papakostidis C, Kanakaris NK, Giannoudis PV. Pelvic ring disruptions: treatment modalities and analysis of outcomes. *Int Orthop.* 2009;33:329–38.
12. Kalmet PHS, van Horn YY, Sanduleanu S et al. Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study. *Arch Orthop Trauma Surg.* 2019;139:483-8.
13. Kubiak EN, Beebe MJ, North K et al. Early weight bearing after lower extremity fractures in adults. *J Am Acad Orthop Surg.* 2013;21:727-38.
14. Consigliere P, Iliopoulos E, Ads T, Trompeter A. Early versus delayed weight bearing after surgical fixation of distal femur fractures: a non-randomized comparative study. *Eur J Orthop Surg Traumatol.* 2019;29:1789-94.
15. Smeeing DPJ, Houwert RM, Briet JP et al. Weight-bearing or non-weight-bearing after surgical treatment of ankle fractures: a multicenter randomized controlled trial. *Eur J Trauma Emerg Surg.* 2020;46:121-30.
16. Kalmet PHS, Meys G, v Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg.* 2018;18:8.
17. Doyle DJ, Garmon EH. American Society of Anesthesiologists Classification (ASA Class). StatPearls. Treasure Island, FL: Stat-Pearls Publishing StatPearls Publishing LLC. 2018.
18. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40:373-83.
19. Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther.* 1999;79:371-83.
20. Ware JE, Keller SD. How to score the SF-12 physical and mental health summaries: a user's manual. Boston: New England Medical Centre. 1995.
21. Breivik H, Borchgrevink PC, Allen SM et al. Assessment of pain. *Br J Anaesth.* 2008;101:17-24.
22. Braun BJ, Bushuven E, Hell R et al. A Novel Tool for Continuous Fracture Aftercare - Clinical Feasibility and First Results of a New Telemetric Gait Analysis Insole. *Injury.* 2016;47:490-4.

23. Repo JP, Barner-Rasmussen I, Roine RP et al. Treatment of compound tibia fracture with microvascular latissimus dorsi flap and the Ilizarov technique: A cross-sectional study of long-term outcomes. *J Plast Reconstr Aesthet Surg.* 2016;69:524-32.
24. Garner MR, Thacher RR, Ni A et al. Elective removal of implants after open reduction and internal fixation of Tibial Plateau fractures improves clinical outcomes. *Arch Orthop Trauma Surg.* 2015;135:1491-6.
25. von Rüden C, Wenzel L, Becker J et al. The pararectus approach for internal fixation of acetabular fractures involving the anterior column: evaluating the functional outcome. *Int Orthop.* 2019;43: 1487-93.
26. Kerschbaum M, Hausmann N, Worlicek M et al. Patient-related outcome of unstable pelvic ring fractures stabilized with a minimal invasive screw-rod system. *Health Qual Life Outcomes.* 2017;15:248.
27. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. *Injury.* 2008;39:725–7.
28. Black JD, Bhavikatti M, Al-Hadithy N et al. Early weight-bearing in operatively fixed ankle fractures: a systematic review. *Foot (Edinb).* 2013;23:78-85.
29. Williamson M, Iliopoulos E, Jain A et al. Immediate weight bearing after plate fixation of fractures of the tibial plateau. *Injury.* 2018;49:1886-90.
30. Klein-Nulend J, Bacabac RG, Mullender MG. Mechanobiology of Bone Tissue. *Pathol Biol.* 2005;53: 576-80.

Appendix 7.1

Patients' self-perceived outcome levels in the PWB and RWB groups

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Total LEFS (ADL) (SD):				<0.01
LEFS: week 2	20.3 (11.0)	10.4 (4.4)	15.4 (9.7)	<0.01
LEFS: week 6	38.8 (12.8)	16.3 (6.1)	27.6 (15.1)	<0.01
LEFS: week 12	52.9 (12.3)	32.5 (12.7)	42.7 (16.1)	<0.01
LEFS: week 26	61.5 (12.2)	48.9 (13.4)	55.2 (14.3)	<0.01
Total SF-12 (quality of life) (SD):				<0.01
SF-12: week 2	40.0 (17.3)	28.8 (12.3)	34.4 (16.0)	<0.01
SF-12: week 6	59.3 (16.2)	38.7 (16.3)	49.0 (19.2)	<0.01
SF-12: week 12	69.3 (20.6)	54.2 (16.2)	61.7 (20.0)	<0.01
SF-12: week 26	79.5 (19.0)	69.3 (22.2)	74.4 (21.2)	<0.01
Total SF-12 PCS:				<0.01
PCS: week 2	23.9 (16.4)	9.8 (5.7)	16.9 (14.1)	<0.01
PCS: week 6	48.6 (17.9)	19.8 (11.2)	34.2 (20.7)	<0.01
PCS: week 12	63.9 (23.3)	39.7 (18.6)	51.8 (24.3)	<0.01
PCS: week 26	74.8 (23.8)	60.4 (25.8)	67.5 (25.7)	<0.01
Total SF-12 MCS:				0.11
MCS: week 2	56.2 (23.5)	47.7 (22.5)	51.9 (23.3)	
MCS: week 6	70.0 (19.8)	57.5 (25.3)	63.8 (23.4)	
MCS: week 12	74.7 (22.5)	68.7 (19.1)	71.7 (21.0)	
MCS: week 26	84.2 (18.9)	78.2 (22.0)	81.2 (20.7)	
Mean NRS (pain) (SD):				0.09
NRS: week 2	3.3 (1.9)	3.5 (2.3)	3.4 (2.1)	
NRS: week 6	2.4 (1.8)	2.7 (2.2)	2.5 (2.0)	
NRS: week 12	2.7 (2.1)	3.1 (2.0)	2.9 (2.1)	
NRS: week 26	1.7 (2.0)	2.8 (2.3)	2.3 (2.2)	

Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; LEFS, lower extremity functional scale; ADL, activities of daily living, SD, standard deviation; PCS, physical composite score; MCS, mental composite score; NRS, numeric rating scale.

Appendix 7.2

Weight-bearing compliance in the PWB and RWB groups

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Mean WB, newton (SD)				0.06
Mean WB: week 2-4	253.03 (166.6)	182.08 (284.1)	216.62 (235.6)	
Mean WB: week 4-6	330.34 (232.4)	220.08 (305.1)	270.88 (278.1)	
Mean WB: week 6-8	335.19 (205.4)	232.38 (158.1)	273.81 (184.3)	
Mean WB: week 8-10	437.87 (252.3)	294.33 (196.3)	342.18 (224.3)	
Mean WB: week 10-12	381.09 (208.2)	287.00 (181.8)	317.18 (193.8)	
Peak loading, newton (SD)				0.05
Peak loading: week 2-4	1,362.51 (666.0)	618.78 (639.1)	976.16 (748.1)	
Peak loading: week 4-6	1,531.21 (717.2)	959.08 (879.2)	1,229.43 (852.2)	
Peak loading: week 6-8	1,675.68 (698.4)	1,131.13 (759.2)	1,340.57 (778.1)	
Peak loading: week 8-10	2,025.20 (888.1)	1,432.55 (769.3)	1,625.80 (847.9)	
Peak loading: week 10-12	1,738.88 (757.0)	1,426.72 (807.5)	1,526.85 (798.0)	

Abbreviation: PWB, Permissive weight bearing; RWB, Restricted weight bearing; N, number of subjects; SD, standard deviation; WB, Weight bearing in newton on affected leg; Peak loading, Peak loading in newton on affected leg.



Chapter 8

Permissive weight bearing in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is cost-effective: a prospective comparative multicenter cohort study

Kalmet PHS
Maduro CV
Andriessen MT
Moens-Oyen CPA
Hiligsmann MJC
van Vugt R
Janzing H
Jaspars C
Sintenie JB
van der Veen A
Seelen HAM
Blokhuys TJ
Brink PRG
Poeze M
Evers SMAA

Submitted

Abstract

Introduction

The actual guidelines concerning the aftercare of surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities advocate restricted weight bearing (RWB). The aim of this study was to compare the cost-effectiveness and the cost-utility of a new permissive weight bearing (PWB) protocol with the standard RWB protocol from both a societal and a hospital perspective.

Materials and methods

This prospective comparative cohort study included surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities followed by PWB or RWB. Costs, Activities of Daily Living (ADL) and quality of life were measured during 26 weeks (at baseline, 2, 6, 12 and 26 weeks post-surgery). Cost per quality adjusted life year (QALY) gained (cost-utility) and cost per ADL or Life Years (cost-effectiveness) were estimated. Bootstrapping and sensitivity analyses were conducted to characterize uncertainty.

Results

This study included 106 trauma patients (N=53 in both the PWB and the RWB-group). There were no significant group differences in baseline characteristics. Costs were lowest for the PWB group (€9,379.45 vs €9,836.96) during 26 weeks post-surgery.

Conclusions

PWB is more cost-effective compared to the RWB regimen. Moreover, the PWB-group showed more improvement in ADL compared to the RWB-group.

Introduction

Annually, about 19% of patients who suffer a fracture have surgery because of peri- and/or intra-articular fractures of the lower extremities.¹ These patients often suffer from sequelae and need long-term rehabilitation. The current postoperative management in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is either non-weight bearing or restricted (or partial) weight bearing.^{2,3} According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Principles of Fracture Management, postoperative management of peri- and/or intra-articular fractures of the lower extremities consist of non-weight bearing for 6-12 weeks, followed by partial weight bearing with a 25% increase in weight every week.² Full weight bearing in this method will be reached per protocol after 10-16 weeks post-surgery, but in practice may take significantly more time.^{4,5}

Both the current non-weight bearing postoperative management and the complications in trauma patients with peri- and/or intra-articular fractures of the lower extremities are often associated with a longer period of postoperative rehabilitation, and with lasting impairments. Moreover, estimates of medical costs and economic production losses to society due to trauma clearly warrant close attention from both health policy makers and the medical profession.⁶

The current non-weight bearing protocols are being disputed. Studies report positive effects e.g. less complications, reduced hospital stay, and a decrease in productivity loss due to an early or permissive weight bearing protocol.^{3,5-12} A recent study in surgically treated tibial plateau fractures found a 6 weeks shorter time to full weight bearing in the permissive weight bearing group (PWB) versus restricted weight bearing (RWB), 14.7 versus 20.7 weeks, respectively.⁵ However, despite the increasing importance of economic considerations in policy decision making, the cost-effectiveness of PWB compared to RWB is yet unknown.

Therefore, the aim of the present study was to compare the cost-effectiveness and the cost-utility of the PWB protocol with the RWB protocol from both a societal and a hospital perspective.

Patients and methods

This prospective comparative multicenter cohort study included surgically treated trauma patients with peri- and/or intra-articular fractures of the pelvis/acetabulum and the lower extremities. Subjects were consecutively recruited from six hospitals in the

Netherlands (i.e. Maastricht University Medical Center+, Maastricht; Zuyderland Medical Center, Heerlen; Catharina Hospital, Eindhoven; Elkerliek Hospital, Helmond; VieCuri Medical Center, Venlo and Maxima Medical Center, Veldhoven) between October 2017 and September 2018 (Figure 8.1). All patients who were treated in Maastricht University Medical Center+ and Zuyderland Medical Center underwent the PWB protocol⁵ as aftercare rehabilitation treatment, whereas the others followed the RWB² protocol.

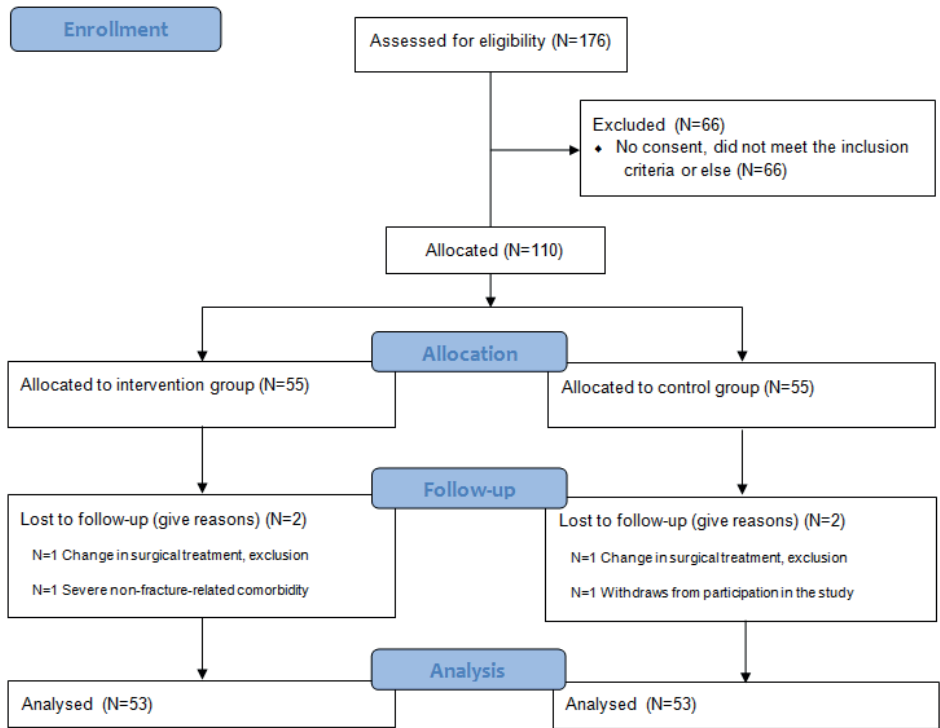


Figure 8.1 CONSORT Flowchart of study patients.

Surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities (i.e. pelvic fractures, acetabular fractures, distal femur fractures, tibial plateau fractures, pilon fractures, calcaneal fractures and talar fractures) were eligible for inclusion if they were 18 years or older. Patients with pathological fractures, shaft fractures treated with intra-medullary nailing, or fractures treated with external fixation, and patients with amputations in the area of the lower extremity, were excluded. Patients with cognitive dysfunction due to the consequences of a severe neurotrauma or to concomitant or mental illness were also excluded.¹³

The PWB treatment involves a gradual progression in functional activities guided by patients' subjective experience (pain and confidence to bear weight) and by objective clinical symptoms of the patients occurring during the process of rehabilitation. Clinical symptoms include the evolution of signs of inflammation, neuro-vascular status, weight-bearing tolerance, changes in the alignment of the affected side of the body, and the quality and function of the soft tissue and the joints involved. This progression in patients' functional activities is determined from the quality of performance of a functional activity. The progress in therapy is not determined by any predetermined or fixed degree of loading of the affected side in kg or in percentage of body weight, as this has proved to be difficult to adhere to. This process enables patients to carry out the activities with normal/optimal motor skills as soon as possible. The approach is guided by the quality of performance and the safety of the activity (e.g. preventing stumbling). The next stage of the treatment is started when the gait pattern associated with the current stage of the treatment is optimally executed, and can be performed by the patient safely and independently.⁵ The PWB treatment involves multidisciplinary collaboration with surgeons, rehabilitation physicians and physical therapists, which is considered paramount to safely use the PWB protocol.⁵ In the RWB group, the patients underwent a non-weight bearing regime for 6–12 weeks followed by partial weight bearing with a 25% increase in weight loading every week according to the existing (AO-) guidelines.²

The baseline characteristics in the study were collected from the electronic medical records by two researchers (PK and CM). Baseline characteristics included: age at time of fracture, gender, ASA (American Society of Anesthesiologists, assessing the fitness of patients before surgery, type 1–6),¹⁴ Charlson-comorbidity score (classifying prognostic comorbidity, a higher score representing additional comorbidities),¹⁵ type of fracture and the length of hospital stay (in days).

Economic outcomes

This study includes a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). The outcome measure of the cost-effectiveness analysis (CEA) was the patient-self-perceived outcome questionnaire, a measure for the Activities of Daily Living (ADL). The patient's self-perceived outcome questionnaire was taken at week 2, 6, 12 and 26 post-surgery. The ADL was measured with the Lower Extremity Functional Scale (LEFS). The LEFS consists of 20 questions about a person's ability to perform daily tasks. Each question can be scored from 0 to 4, where 0 represents the extreme difficulty to perform the activity. The maximum possible score is 80 points. The lower the score, the greater the disability.¹⁶

The clinical effectiveness of the PWB protocol and the RWB protocol was determined according to the results of the LEFS.¹⁶ The outcome of the CUA were the quality adjusted life years (QALYs). The QALYs were calculated based on EQ-5D score and life years. Health status was measured using the five dimensional health state description of the EQ-5D.¹⁷ Besides, the quality of life was measured with the Short Form-12 (SF-12) questionnaire. The SF-12 consists of 12 items that assess 8 dimensions of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The SF-12 measures various aspects of physical and mental health from which a physical composite score (PCS) and a mental composite score (MCS) can be calculated, ranging from 0 to 100.¹⁸ All measures were registered by a self-completion questionnaire at baseline and at 6, 12 and 26 weeks follow-up. By using the Dutch Tariff for the EQ-5D,¹⁷ health states were converted into quality adjusted life years (QALYs). QALYs were calculated using the total-area-under-the-curve approach.¹⁷

Costs

The costs were determined from the societal and hospital perspective and were divided into four parts: (a) health care costs, (b) patient & family costs, (c) costs associated with productivity losses, and (d) PWB costs. The iMTA (Institute for Medical Technology Assessment) Medical Consumption Questionnaire (iMCQ) measured all healthcare consumption by the participants during the end of 26 weeks of follow-up and included medication costs, visits with General Practitioners (GP), medical specialists, occupational physicians, therapists (physical therapists, dieticians, occupational therapists, speech therapists, homeopaths and psychologists), social workers, emergency rooms visits, ambulance transportation, hospital admittance, homecare (domestic help, help with ADL and nursing), admittance in rehabilitation centers and admittance in assisted living centers.¹⁹ Patient and family costs were derived from the iMCQ and consisted of travel costs. The iMTA (Institute for Medical Technology Assessment) Productivity Cost Questionnaire (iPCQ) measured work absence and the number of hours the participant was replaced for unpaid work (for patients in paid employment), production losses to society due to absenteeism (illness-related absence from work), presenteeism (loss of productivity while at work), and compensation for diminished productivity. Diminished productivity due to absence from work may be compensated when lost work can be made up by the sick employees themselves or taken over by other employees within the company during normal working hours.²⁰

Following Dutch guidelines on economic healthcare evaluations, a bottom-up approach was used for this study.^{21,22} For the valuation of costs, the reference prices from the Dutch costing guideline were used.²³ These reference prices were multiplied by the average healthcare consumption as measured with the iMCQ and iPCQ. In

concordance with the guidelines, all hours of unpaid work were valued as replaced by paid help.²³ The costs of medication were based on the price per dosage. Prescription costs were added for all medications except for over-the-counter drugs. Costs were, where necessary, indexed for the year 2018 (in Euros).

Due to the lack of information about the travel arrangements of the family members, the assumption was made that they only traveled by car. For the travel tariffs the distinction was made between hospital visits and non-hospital visits. Tariffs were provided by the Dutch guidelines.^{21,22} All costs were indexed for inflation to the year 2018 using the consumer price index.²⁴ Discount rates did not apply due to the time horizon of 26 weeks.

Economic analysis

For the CEA, we calculated the incremental cost and effectiveness of the PWB compared to the RWB. Incremental costs are defined as the mean difference between both groups in total costs over 26 weeks post-surgery. Incremental effectiveness is the mean difference in the LEFS over 26 weeks post-surgery. The incremental cost-utility was calculated as the difference in total costs divided by the difference in QALYs. The Incremental Cost-Effectiveness Ratios (ICERs) were given as costs (€) per unit improvement on the LEFS and costs (€) per QALY.

All analyses were performed according to the intention-to-treat principle. Clinical difference between the PWB group and the RWB group, were assessed using a linear mixed-effects regression model in IBM SPSS Statistics, Version 25.0, Armonk, New York.

As costs data are generally skewed and not distributed normally, non-parametric bootstrap re-sampling techniques were performed in STATA 14, with 5,000 replications to estimate cost-effectiveness uncertainty intervals around the ICERs.^{25,26} Bootstrapping is a non-parametric way to repeatedly conduct an analysis by resampling, with replacement, from the observed data.²⁷ Seemingly unrelated regression equations (SURE) were bootstrapped (5,000 times) to allow for correlated residuals of the cost and utility equations. The uncertainty interval is represented by the 2.5th and 97.5th percentiles. The results of ICER bootstraps are presented in cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs).²⁸ Cost-effectiveness planes show differences in effect on the horizontal axis and costs on the vertical axis. Bootstrapped cost-effectiveness pairs located in the northwest quadrant indicate the PWB to be inferior to conventional care (more costly and less effective); in the south-east quadrant to be dominant (more effective and less costly); and with respect to the north-east and south-west quadrant, the preference for an intervention depends on the threshold value, that is, what society is prepared to pay for an

effectiveness gain, or willing to accept as savings for effectiveness loss. The CEAC represents the probability that, given a certain threshold for the willingness to pay for an extra point on the LEFS or for a QALY, the intervention is cost-effective. A CEAC is constructed by taking certain thresholds (€) and calculating the percentage of the 5,000 bootstrapped ICERs that are below each threshold, and therefore cost-effective, given that threshold. Due to uncertainty on the monetary threshold per QALY gained, alternative values ranging from € 0 to €80,000 were used in the cost-utility analysis.²⁹ However, the exact threshold value is unknown, and there are no exact guidelines available in the Netherlands. Although in general €18,000 is accepted as the threshold value per QALY for preventive care in the Netherlands.²⁹ However, the Dutch Council for Public Health and Health Care recommends relating the threshold of the costs of a QALY to the burden of disease, with a limit of €80,000 per QALY for diseases with a maximum loss in health status.²⁹ Despite the absence of clear guidelines, we have chosen for a €50,000 threshold, which will be broad enough to capture the relevant threshold values in this study. Since the value that society might place on a unit reduction in LEFS score is unknown, its benefit cannot be defined.

Finally, sensitivity analyses were performed. The base case includes all patients including those with and without paid job. A sensitivity analysis to assess the difference between these groups was conducted. The approach was similar to that of the base case. The outcomes were compared with the outcomes of the base case. Also, to provide a broader coverage of important health domains and scores for various purposes³⁰ when calculating the cost-utility, a sensitivity analysis was conducted using scores from the SF-12 to calculate the QALYs gained instead those of the EQ-5D. In the base-case analysis, regression correction was used for the baseline costs and QALYs. Lastly, a sensitivity analysis including only healthcare costs was conducted. To conduct a sensitivity analysis only the healthcare costs were considered when calculating the cost-effectiveness and the cost-utility.

The medical ethics committee of Maastricht University Medical Center, Maastricht, the Netherlands approved this study, reference number: METC 16–4-236. Patient's informed consent to participate was obtained from all patients.

Results

Baseline characteristics participants

This cohort study included 106 patients, N=53 both in the PWB and the RWB group. No significant differences in gender, age, employee, ASA type, type of fracture, number of surgical interventions and in hospital length of stay were found between the PWB and

RWB groups. Characteristics of patients in the PWB and RWB group are summarized in Table 8.1.

Table 8.1 Baseline characteristics and in hospital outcome of the PWB and RWB groups.

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Female, N	27 (50.9%)	27 (50.9%)	54 (50.9%)	1.00
Median age (IQR), years	55.0 (38.5-65.0)	60.0 (47.0-67.0)	58.0 (43.5-66.3)	0.27
Employee, N	27 (50.9%)	26 (49.1%)	53 (50.0%)	0.99
ASA, N				0.14
I, II	49 (92.5%)	44 (83.0%)	93 (87.7%)	
III >	4 (7.5%)	9 (17%)	13 (12.3%)	
Median Charlson score (IQR)	1 (0-3)	2 (1-3)	2 (0-3)	0.03
Fracture type, N:				0.18
Pelvic	7 (13.2%)	1 (1.9%)	8 (7.5%)	
Acetabular	5 (9.4%)	3 (5.7%)	8 (7.5%)	
Tibial plateau	16 (30.2%)	28 (52.8%)	44 (41.5%)	
Pilon	17 (32.1%)	12 (22.6%)	29 (27.4%)	
Calcaneal	8 (15.1%)	9 (17.0%)	17 (16%)	
In hospital outcome:				
2 or more procedures (%)	9 (17.0)	8 (15.1)	17 (16.0)	0.57
Median length of stay (IQR), in days	7.0 (2.0-15.5)	5.0 (2.0-11.5)	6.0 (2.0-14.0)	0.24

Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; ASA, American Society of Anesthesiologists; IQR, interquartile range.

A flow diagram of the participants is shown in Figure 8.1. After a follow-up of 26 weeks post-surgery, the overall response rate of the patients' self-perceived outcome levels at all measurement points was 99.8% (N=1 patient refused to fill out the patient self-perceived outcome questionnaires at week 26).

ADL, as measured with the LEFS, and quality of life, as measured with the SF-12 and the EQ-5D, were all significantly increased in the PWB group compared to the RWB group ($p<0.01$) over a period of 26-weeks post-surgery. Furthermore, full weight bearing was achieved faster in the PWB group compared to the usual RWB regime ($p<0.01$).

The utility scores derived from the LEFS are presented in table 2; the mean LEFS in the PWB group was significantly higher at all follow-up moments compared to the RWB group. The sensitivity analysis between patients with paid job and patients without paid job showed a significant difference between the PWB and RWB groups at follow-up week 6, 12 and week 26. The mean utility score for both the PWB and RWB groups increased significantly at follow-up week 12 and 26. Furthermore, significant differences in QALY's between the groups were found (see Table 8.2).

Table 8.2 Outcomes base case and sensitivity analysis scenarios.

	PWB (N=53)				RWB (N=53)				p	
	FM ^e	FU W6	FU W12	FU W26	FM ^e	FU W6	FU W12	FU W26	PWB	RWB
LEFS (SD)										
Total LEFS-scores in patients with paid job	22.15 (12.15)	43.00 ^b (13.71)	54.07 (13.17)	65.81 (13.03)	9.96 (5.11)	15.07 (6.97)	29.48 (14.59)	52.96 (11.41)	<0.01 ^{f,g}	<0.01 ^{f,g}
Total LEFS-Scores in patients without paid job	18.35 (9.63)	34.46 ^b (10.21)	51.58 (11.45)	57.46 (9.67)	10.92 (3.54)	17.54 (5.14)	35.54 (9.82)	46.26 (14.04)	<0.01 ^{f,g}	<0.01 ^{f,g}
Total LEFS-scores	20.28 ^a (11.05)	38.8 ^a (12.75)	52.85 ^a (12.30)	61.53 (12.02)	10.43 ^a (4.40)	16.28 ^a (6.21)	32.45 ^a (12.73)	49.54 (13.14)	<0.01 ^{f,g}	<0.01 ^{f,g,h}
Utility scores (SD)										
Utility scores in patients with paid job	0.49 (0.22)	0.73 (0.13)	0.82 (0.10)	0.89 (0.15)	0.32 (0.13)	0.40 (0.10)	0.67 ^b (0.15)	0.80 ^b (0.068)	<0.01 ^g	<0.01 ^g
Utility scores in patients without paid job	0.38 (0.24)	0.70 (0.16)	0.80 (0.13)	0.81 (0.17)	0.25 (0.19)	0.32 (0.24)	0.52 ^b (0.26)	0.68 ^b (0.29)	0.01	
Total Utility scores	0.44 ^a (0.23)	0.72 ^a (0.14)	0.81 ^a (0.11)	0.85 ^a (0.16)	0.28 ^a (0.16)	0.36 ^a (0.19)	0.59 ^a (0.22)	0.74 ^a (0.22)	<0.01	
QALY (SD)										
Total QALY in patients with paid job		0.018 (0.017)	0.06 (0.043)	0.017 (0.027)		0.006 (0.010)	0.07 (0.035)	0.035 (0.036)	<0.01 ^f	<0.01 ^f
Total QALY in patients without paid job		0.025 (0.016)	0.081 (0.049)	0.003 (0.05)		0.006 (0.017)	0.05 (0.051)	0.045 (0.080)		
Total QALY ^{c,d}		0.021 ^a (0.017)	0.072 ^a (0.047)	0.01 (0.04)		0.006 ^a (0.139)	0.059 ^a (0.045)	0.040 (0.062)		

^a Sig. difference between PWB and RWB at 5% level; ^b Sig. Difference in group between patients with paid job and patients without paid job at 5% level; ^c Total QALYs are calculated over 12 weeks (max. QALY is 0.23); ^d QALY calculated according to NL-tariff; ^e First Measurements were conducted 2 weeks after initial injury; ^f Between FM and FU W6; ^g Between FU W6 and FU W12; ^h Between FU W12 and FU W26.

Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; SD, standard deviation; FM, First measurement; FU, follow-up; W, week; LEFS, lower extremity functional scale; QALY, quality adjusted life year.

Costs

Volumes of cost items during the 3-month pre-trauma period were low and comparable between the groups (Table 8.3). From the total population 77.4% of the patients (N=82) reached full weight bearing within 12 weeks. The number of patients who reached full weight bearing within 12 weeks was significantly higher in the PWB group than in the RWB group: 98.1% versus 56.6% ($p<0.01$). The median time from surgery to ascertainment of full weight bearing was significantly shorter in the PWB group than in the RWB group: 4.0 (2.1) weeks versus 12.2 (4.2) weeks ($p<0.01$). Furthermore, the total outpatient physiotherapy duration in the PWB was significantly lesser compared to the RWB group. The incidence of postoperative complications of the total study population was 16.0%. No significant differences between the PWB group and the RWB group were found regarding the incidence of postoperative complications (11.3% (N=6) versus 20.8% (N=11), respectively ($p=0.19$). Results from rehabilitation outcome measures and post-operative complications in patients in the PWB and RWB group are summarized in Table 8.4.

After a follow-up of 26 weeks post-surgery, the total mean costs per patient were €457.51 lower in the PWB group than in the RWB group (see Table 8.3). The cost of production losses due to absence from work was €1,440.92 lower in the PWB group compared to the RWB group.

Cost-effectiveness analysis

For both the base case as the sensitivity analysis the PWB can be considered cost-effective with a cost saving per gained score on the LEFS for the base case and slight costs per gained point for the sensitivity analysis scenarios. Cost-effectiveness based on QALYs for the base case can be considered because the incremental value is below the set threshold of €50,000 (see Table 8.5). Based on this threshold, the probability that the PWB protocol is cost-effective at 26 weeks post-surgery is 66%, from a societal perspective (Figure 2). The sensitivity analysis scenarios, based on the work status and the SF-12 questionnaire, are above the threshold of €50,000 or inferior to the CAU (see Table 8.5).

Table 8.3 Costs (in Euro) per group in base case and sensitivity analysis scenario.

	PWB (N=53)			Total after 26 weeks	RWB (N=53)		
	FM	FU W 0-12	FU W 13-26		FM	FU W 0-12	FU W 13-26
Healthcare (SD)							
Patients with paid job	441.95 (1,436.64) ^{440.80}	5,130.09 (4,609.62) ^{5,091.75}	650.10 (569.15) ^{628.15}	5,780.19 (5,178.77)	150.60 (338.43) ^{151.18}	4,413.50 (3,231.64) ^{4,412.89}	701.45 (435.36) ^{693.85 a}
Patients without paid job	251.67 (349.22) ^{354.07}	7,421.39 (5,219.40) ^{7,382.54}	571.89 (375.24) ^{542.92}	7,993.28 (5,594.64)	302.20 (413.20) ^{301.24}	7,479.63 (9,076.19) ^{7,518.62}	861.35 (701.75) ^{861.44 a}
Total	348.61 (1,048.72) ^{345.54}	6,254.12 (5,005.87) ^{5,911.03}	611.73 (480.85) ^{644.85 a}	6,865.85 (5,486.72)	227.83 (382.47) ^{228.68}	5,975.49 (6,971.67) ^{6,239.71}	782.91 (586.40) ^{670.04 a}
Productivity Loss (SD)							
Patients with paid job	172.69 (852.30) ^{178.17}	2,319.92 (3,611.31) ^{3,309.19}	592.84 (1,319.40) ^{848.64 a}	2,912.76 (4,930.71)	121.75 (465.88) ^{124.18}	3,500.04 (3,462.10) ^{3,506.63}	853.64 (1,707.10) ^{811.88 a}
Patients without paid job	31.48 (160.52) ^{30.41}	155.08 (313.72) ^{178.37}	424.31 (2,152.16) ^{358.16 a}	579.39 (2,465.88)	0.00 (0.00) ^{0.00}	1,011.87 (1,363.51) ^{1,001.61}	341.70 (555.76) ^{311.11 a}
Total	103.42 (617.00) ^{105.97}	1,716.41 (2,993.45) ^{1,731.07}	510.17 (1,761.94) ^{594.49 a}	2,226.58 (4,755.39)	59.72 (328.82) ^{57.44}	2,232.48 (2,875.60) ^{2,222.13}	592.84 (1,273.67) ^{698.83 a}
Patient-family (SD)							
Travel	10.57 (20.29) ^{13.62}	148.80 (63.84) ^{149.21}	138.23 (66.13) ^{139.71}	287.03 (129.97)	13.78 (33.75) ^{13.64}	133.51 (76.07) ^{133.93}	119.72 (82.60) ^{133.09}
Total average costs (SD)							
Patients with paid job	621.18 (2,276.36) ^{635.90}	8,494.76 (6,155.31) ^{8,163.74}	1,381.14 (1,625.57) ^{1,058.37 a}	9,875.90 (7,780.88)	285.63 (630.48) ^{282.95}	8,033.02 (4,917.43) ^{8,098.83}	1,661.28 (1,913.36) ^{2,160.18 a}
Patients without paid job	297.89 (422.11) ^{397.09}	7,729.46 (5,247.06) ^{7,737.99}	1,134.45 (2,385.81) ^{1,050.49 a}	8,863.91 (7,632.87)	316.45 (435.85) ^{321.44}	8,638.52 (9,327.63) ^{8,668.88}	1,335.82 (1,035.01) ^{1,340.20 a}
Total	462.59 (1,644.14) ^{457.59}	8,119.33 (5,685.91) ^{8,067.38}	1,260.12 (2,018.25) ^{1,380.79 a}	9,379.45 (7,704.16)	301.33 (535.10) ^{398.46}	8,341.48 (7,431.10) ^{8,326.70}	1,495.48 (1,524.03) ^{1,480.56 a}

^aSig. difference in group between patients with paid job and patients without paid job at 5% level. X² Bootstrap Value

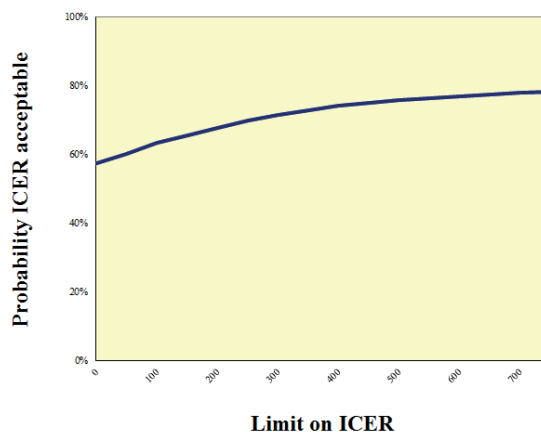
Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; SD, standard deviation; FM, First measurement; FU, follow-up; W, week.

Table 8.4 Rehabilitation outcome measures and post-operative complications in the PWB and RWB groups.

	PWB (N=53)	RWB (N=53)	Total (N=106)	p
Rehabilitation outcome measures:				
Median OPD (IQR), in hours	25 (13.0-46.8)	41 (28.5-57.5)	33 (18.5-52.0)	0.01
FWB within 12 weeks (%), N	52 (98.1)	30 (56.6)	82 (77.4)	<0.01
Median time to FWB (IQR), in weeks	4.0 (2.0-7.0)	13.0 (9.0-15.0)	8.0 (4.0-13.0)	<0.01
N who completed rehabilitation within 26 weeks (%)	30 (65.2)	16 (34.8)	46 (43.4)	<0.01
Total post-operative complications (%)	6 (11.3)	11 (20.8)	17 (16.0)	0.19
Non-unions	0 (0.0)	1 (1.9)	1 (0.9)	
Secondary dislocations	1 (1.9)	2 (3.8)	3 (2.8)	
Superficial wound infections	3 (5.7)	6 (11.3)	9 (8.5)	
Deep wound infection	1 (1.9)	1 (1.9)	2 (1.9)	
Removal of osteosynthesis material	1 (1.9)	1 (1.9)	2 (1.9)	

Abbreviation: PWB, permissive weight bearing; RWB, restricted weight bearing; N, number of subjects; IQR, interquartile range; OPD, outpatient physiotherapy duration; FWB, full weight bearing.

A



B

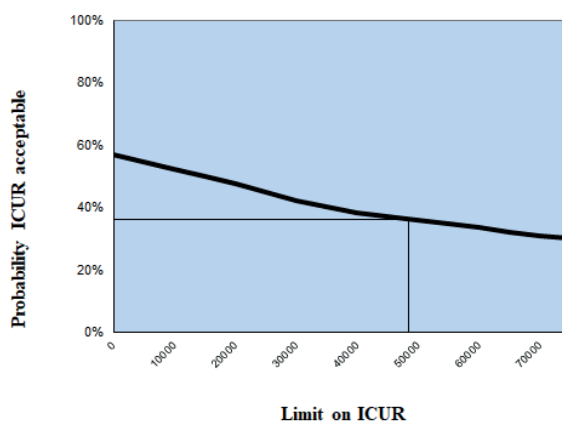


Figure 8.2 A. Cost-effectiveness acceptability curve ICER total costs. B. Cost-effectiveness acceptability curve ICUR total costs..

Table 8.5 Incremental cost-effectiveness and cost-utility ratios - 26 weeks for base case and sensitivity analysis scenarios.

	Societal perspective (€/LEFS-point)	Healthcare perspective (€/LEFS)
ICER total	Dominant	Dominant
ICER patients with paid job	317.6 ^a	Dominant
ICER patients without paid job	Dominant	Dominant
	Societal perspective (€/QALY)	Healthcare perspective (€/QALY)
ICUR total	15,423.9 ^a	162,988.6
ICUR patients with paid job	Inferior	114,218.3
ICUR patients without paid job	1,923,668.0 ^a	3,233,737.4

^a Bootstrap Value

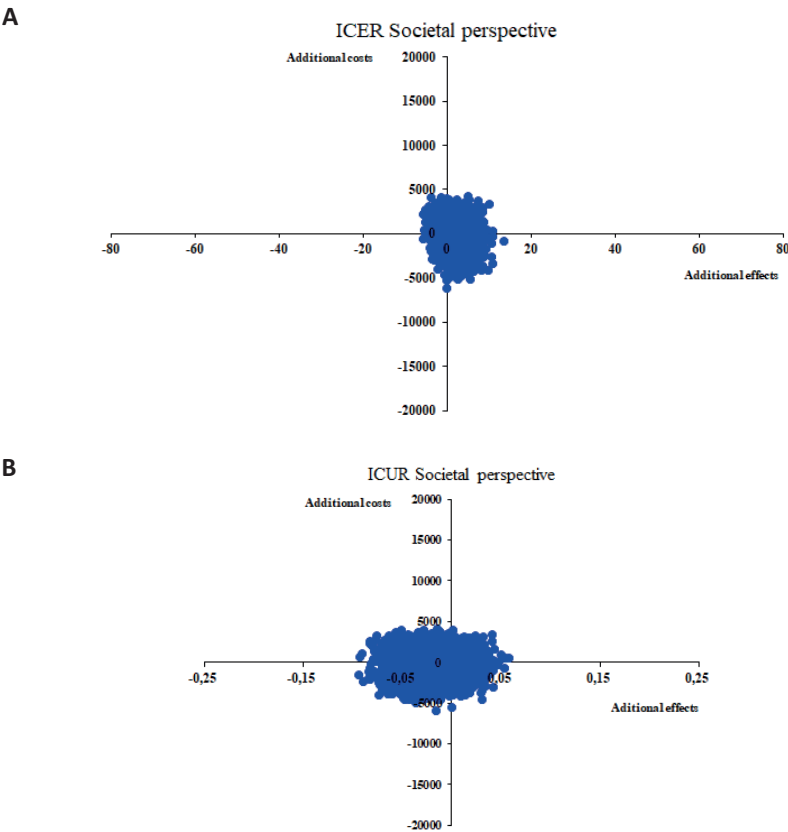


Figure 8.3 **A:** Cost-effectiveness plane for LEFS at week 26 follow-up. North-east: 34.0%; north west: 9.0%; south west: 8.0% and south east: 49.0% (costs per 1 LEFS gained), **B.** Cost-effectiveness plane for QALY at week 26 follow-up (cost per QALY gained). North east: 8.0%; north west: 35.0%; south west: 46.0%; south east: 11.0%.

Discussion

The main goal of this prospective comparative multicenter cohort study was to determine whether permissive weight bearing in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is preferable in terms of costs, effects and utilities, from a societal perspective, compared to the restricted weight bearing protocol. The patients' self-perceived outcome levels (activities of daily living (ADL), quality of life, pain), weight bearing and postoperative complications have been compared between groups following a PWB regimen and restricted weight bearing (RWB) regimen over a period of 26-weeks post-surgery. The novel permissive weight bearing (PWB) regimen led to the patients being able to bear full weight on their affected leg much sooner with a better ADL and quality of life, as compared to those that followed the usual RWB regimen. Furthermore, no differences were found in either postoperative complication rates or pain levels between both treatment regimes. Total costs were lower in the PWB group than in the RWB group. In terms of cost per improvement in LEFS, the PWB group showed higher effects and lower costs, resulting in an ICER of €1,945 per improvement on the LEFS. However, in the absence of a willingness-to-pay threshold for such a clinical measure, no statements regarding its cost-effectiveness can be made. Looking at the quality of life, the PWB group had comparable QALYs to the RWB group with lower costs, resulting in a dominated ICER and ICUR. This indicates that PWB is cost-effective.

In the base-case analysis, regression correction was used for the baseline costs and QALYs. Although utilities did not differ significantly among the groups of patients, it is likely that the patient's baseline utility is highly correlated with the QALY outcome. As shown by the sensitivity analyses, the study results were not heavily affected by specific assumptions, perspectives or inclusion criteria. However, there may be several reasons which could be of influence in the differential effect of PWB. The ADL and quality of life were both significantly increased in the PWB group compared to the RWB group over a period of 26-weeks post-surgery. The median length of stay in the PWB group was 2 days longer compared to the RWB group, which can be related to the slightly higher mean Charlson score in the PWB group. Despite the longer length of stay the patients in the PWB were fully bearing weight 9 weeks faster compared to the RWB group. Also, the outpatient physiotherapy duration was significantly less than in the RWB group. Furthermore, this study found that there was no significant difference in postoperative complications between the PWB group compared to the RWB group. According to recent literature, a composite postoperative complications rate of up to 27.0% has been reported in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities.³¹⁻³⁸ Comparing our complication rates with data published in recent literature, we found lower rates of postoperative complications in

surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities.

Overall PWB is accompanied by less costs over a period of 26-weeks post-surgery. The total costs per patient, consisting of patient-family expenses, healthcare costs and productivity loss, were €457.51 less in the PWB group. Based on the LEFS, PWB seems considerably more effective, as was shown in the base case and in all if the sensitivity analyses. Despite the outcomes of the economic evaluation, there were no significant differences in QALY outcomes, the PWB seems not to achieve much improvement in QALY during the 26 weeks follow-up period. No improvement in QALY's in trauma patients with per-and intra-articular fractures might be the short period of disability and therefore may have lesser impact on the quality of life of a patient.³⁸

In het Netherlands, annually, the incidence of peri- and/or intra-articular fractures of the lower extremities is more than 25,000 patients.¹ This study found that the PWB protocol is €457.51 cheaper compared to the usual current RWB protocol. Annually, this may result in a saving of at least €11,437,750 in the Netherlands.

Our study, the first largest prospective multicenter cohort study comparing PWB with RWB, adds evidence in support of the use of PWB in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities. This study shows that PWB is cost-effective compared to the RWB protocol. To our knowledge, little is known about the cost or cost-effectiveness in trauma patients with peri- and/or intra-articular fractures of the lower extremities, also due to the fact that the PWB protocol is a relatively new protocol. However, studies about early weight bearing have been contesting the current guidelines.^{3,5-12}

Due to the structure of the data collection there was almost no missing data, resulting in no exclusion due to missing data. When interpreting our data, some limitations have to be considered. The non-randomized nature of the study limits the data quality. On the other hand, patients were allocated to the PWB and RWB surgical teams consecutively to avoid selection bias. There were discrepancies regarding the patients' comorbidities and the different hospitals in which the patients were treated. Our statistical analyses took these discrepancies into consideration, thus correcting the presented results for the confounding influence that these factors may have had on the study results. Another limitation was the lower utility scores of the SF-12 versus the ones of the EQ-5D. The question which of the two measured the utility score more accurately was raised for this assessment. It is argued that the EQ-5D has a more general approach, while SF-12 may be better suited to capture certain facets of health status⁴⁰ and therefore may be more sensitive to this population. A combination of the SF-12 and the EQ-5D may provide a relatively broad coverage of important health

domains and scores.⁴¹ Furthermore, a longer follow-up is needed to provide more insight into the long-term cost-effectiveness.

Conclusion

This prospective comparative multicenter study shows that PWB after surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is more cost-effective compared to the RWB regimen. Moreover, the PWB group showed more improvement in ADL and quality of life compared to the RWB group. Looking at the incremental economic analyses, PWB was less expensive and yielded more effects.

References

1. Landelijk netwerk acute zorg. [National network acute care] Landelijke traumaregistratie [National trauma registry] 2010-2014. The Netherlands. 2015. Available from: http://www.lnaz.nl/cms/LNAZ_LTR_rapportage_2010-2014.pdf.
2. Ruedi TP, Buckley RE, Moran CG. AO principles of fracture management. Third edition. New York: Thieme. 2018.
3. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthop Clin N Am*. 2013;44:509–19.
4. Meys G, Kalmet PHS, Sanduleanu S et al. A protocol for permissive weight-bearing during allied health therapy in surgically treated fractures of the pelvis and lower extremities. *J Rehabil Med*. 2019;51:290–7.
5. Kalmet PHS, Van Horn YY, Sanduleanu S et al. Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study. *Arch Orthop Trauma Surg*. 2019;139:483–8.
6. van Beeck EF, van Roijen L, Mackenbach JP. Medical costs and economic production losses due to injuries in the Netherlands. *J Trauma*. 1997;42:1116–23.
7. Kubiak EN, Beebe MJ, North K et al. Early weight bearing after lower extremity fractures in adults. *J Am Acad Orthop Surg*. 2013;21:727–38.
8. Black JD, Bhavikatti M, Al-Hadithy N et al. Early weight-bearing in operatively fixed ankle fractures: a systematic review. *Foot (Edinb)*. 2013;23:78–85.
9. The Canadian Orthopaedic Trauma Society. Open reduction and internal fixation compared with circular fixator application for bicondylar tibial plateau fractures. Results of a multicenter, prospective, randomized clinical trial. *J Bone Jt Surg Am*. 2006;88:2613–23.
10. Solomon LB, Callary SA, Stevenson AW et al. Weightbearing-induced displacement and migration over time of fracture fragments following split depression fractures of the lateral tibial plateau: a case series with radiostereometric analysis. *J Bone Jt Surg Br*. 2011;93:817–23.
11. Williamson M, Iliopoulos E, Jain A et al. Immediate weight bearing after plate fixation of fractures of the tibial plateau. *Injury*. 2018;49:1886–90.
12. Westerman RW, Hull P, Hendry RG, Cooper J. The physiological cost of restricted weight bearing. *Injury*. 2008;39:725–7.
13. Kalmet PHS, Meys G, V Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg*. 2018;18:8.
14. Doyle DJ, Goyal A, Bansal P, Garmon EH. American Society of Anesthesiologists Classification (ASA Class). 2020 Jul 4. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020.
15. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40:373–83.
16. Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther*. 1999;79:371–83.
17. Versteegh, M, Vermeulen K, Evers S et al. Dutch Tariff for the Five-Level Version of EQ-5D. *Value in Health*. 2016;19:343–52.
18. Ware JE, Keller SD. How to score the SF-12 physical and mental health summaries: a user's manual. Boston: New England Medical Centre. 1995.
19. Institute for Medical Technology Assessment, iMTA. iMTA Medical Consumption Questionnaire (iMCQ) (2019). Available from: <https://www.imta.nl/questionnaires/>.
20. Institute for Medical Technology Assessment, iMTA. iMTA Productivity Cost Questionnaire (iPCQ) (2019). Available from: <https://www.imta.nl/questionnaires/>.
21. Zorginstituut Nederland [Dutch Healthcare Institute]. Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg [Guidelines for conducting economic evaluations in health care]. Diemen: 2016.
22. Tarricone R. Cost-of-illness analysis: What room in health economics? *Health policy*. 2006;77:51–63.

23. Zorginstituut Nederland [Dutch Healthcare Institute]. Kostenhandleiding: Methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg [Cost manual: Methodology of cost research and reference prices for economic evaluations in health care]. Diemen: 2015.
24. CBS (2019). Statline, Consumentenprijzen; prijsindex 2015=100. 2016; Retrieved from: <https://opendata.cbs.nl/statline/#/CBS/nl/dataset/83131NED/table?ts=1558081200396>.
25. Briggs AH, Wonderling DE, Mooney CZ. Pulling cost-effectiveness analysis up by its bootstraps: a nonparametric approach to confidence interval estimation. *Health Econ.* 1997;6:327–40.
26. O'Hagan A, Stevens JW. Assessing and comparing costs: how robust are the bootstrap and methods based on asymptotic normality? *Health Econ.* 2003;12:33–49.
27. Obenchain RL, Melfi CA, Croghan TW, Buesching DP. Bootstrap Analyses of Cost Effectiveness in Antidepressant Pharmacotherapy. *PharmacoEconomics.* 1997;11:464–72.
28. van Hout BA, Al MJ, Gordon GS, Rutten FF. Costs, effects and C/E-ratios alongside a clinical trial. *Health Econ.* 1994;3:309–19.
29. Raad voor de Volksgezondheid & Zorg 2014 [cited 2014 27 March]. Available from: http://www.rvz.net/uploads/docs/Advies_-_Rechtvaardige_en_duurzame_zorg.pdf.
30. Hoffman K, Cole E, Playford ED et al. Health Outcome after Major Trauma: What Are We Measuring? *PLoS One.* 2014;9:e103082.
31. Choo K. Postoperative complications after repair of tibial plateau fractures. *J Knee Surg.* 2014;27:11–20.
32. Yu X. Postoperative complications after closed calcaneus fracture treated by open reduction and internal fixation: a review. *J Int Med Res.* 2013;42:14–25.
33. Lee DH, Lee KB, Jung ST et al. Comparison of early versus delayed weightbearing outcomes after microfracture for small to mid-sized osteochondral lesions of the talus. *Am J Sports Med.* 2012;40:2023–8.
34. Jason J. Talar neck fractures: a systematic review of the literature. *J Foot Ankle Surg.* 2013;52:56–61.
35. Lasanianos N. Early mobilization after uncomplicated medial subtalar dislocation provides successful functional results. *J Orthop Traumatol.* 2011;12:37–43.
36. Mario CK. Early mobilization in bilateral talar fractures. *Foot Ankle Online J.* 2014;7:9.
37. Schwabe P. Complications after osteosynthetic treatment of acetabular fractures. *Orthopäde.* 2014;43:24–34.
38. Papakostidis C. Pelvic ring disruptions: treatment modalities and analysis of outcomes. *Int Orthop.* 2009;33:329–38.
39. Sprangers MA, Schwartz CE. Integrating response shift into health-related quality of life research: a theoretical model. *Soc Sci Med.* 1999;48:1507–15.
40. Hoffman K, Cole E, Playford ED et al. Health outcome after major trauma: what are we measuring? *PLoS One.* 2014;9:e103082.
41. Johnson JA, Pickard AS. Comparison of the EQ-5D and SF-12 health surveys in a general population survey in Alberta, Canada. *Med Care.* 2000;38:115–21.



Chapter 9

General discussion

Summary

Samenvatting

Study impact

General discussion

Sixty years ago, a group of 13 Swiss surgeons founded the Arbeitsgemeinschaft für Osteosynthesefragen [Association of Osteosynthesis] (AO) with the aim of improving fracture care.¹ Since the 60 years of its foundation, the AO's impact on science, education, patient care, and the MedTech business has been significant. The main principles of aftercare treatment during this period in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities has been historically non- or restricted weight bearing for 6-12 weeks.² This non- or restricted weight bearing protocol was based on clinical reasoning. The reason for this non or restricted weight bearing protocol was the surgeons' hesitation in allowing early weight bearing after lower extremity fractures in order to limit risks of loss of reduction and implant failure. Studies evaluating this non- or restricted weight bearing protocols are, however, lacking. More recently there has been a renewed clinical interest in earlier start of weight-bearing according to the patient's tolerated pain, feeling of instability, or redness and swelling at the site of the fracture. The term for this aftercare treatment is "permissive weight bearing". Biological advantages of a permissive weight bearing regimen over restricted weight bearing are plentiful, both of which have been observed in biomechanical human and animal studies.^{3,4} Wolff's law⁵ states that bone responds to the mechanical stresses applied to it, allowing it to strengthen over time. At a cellular level, appropriate strain in the fracture gap leads to optimum cellular proliferation of osteoblasts, which orient themselves according to their mechanical environment and other cell lines involved in bone formation.⁶ Several theories exist on the mechanical influences on fracture healing. Two more important ones, perhaps somewhat connected to each other are Perren's classical strain theory (tissue formed in a fracture gap is dictated by the degree of local motion/strain that occurs between the surfaces of the bone) and Claes and Heigele's work (different types of bone formation in fracture healing according to local mechanical influences; bone can be formed under tension or compression, but in either case it needs some sort of external mechanical influence/load in order to promote the fracture healing process).⁶ Numerous studies have shown that an absence of motion at the fracture gap leads to significantly reduced callus volume and slower formation. Kenwright and Gardner⁷ most notably have demonstrated the importance of interfragmentary motion and loading on callus formation in relation to time, showing that early reduced motion led to both lower volume and quality of callus. These advantages span beyond the sole improvement of bone health. In one prospective randomized study, one year after surgery, patients who had undergone anti-gravity treadmill rehabilitation in the first six weeks postoperatively showed better gait than patients in the control group, and those with tibial plateau fractures had less muscle atrophy.⁸

One could argue that if a patient is physically and mentally ready to safely bear weight on the affected leg/side, and given that improved motion is beneficial for bone healing, why should we clinicians slow down the weight bearing process by prohibiting the patient to gradually increase weight bearing at a faster yet safe pace sooner? ⁹

A number of disadvantages of restricted weight bearing are known.¹⁰ First and foremost bed rest and wearing a cast are associated with an evident and time-dependent reduction in bone and muscle mass, atrophy of tendons as well as vascular disturbances and skin changes. In near to zero gravity situations such as a six month journey to the International Space Station (ISS) will render nearly 10% loss in skeletal mass in a healthy astronaut, which will take years to recover. These numbers are close to those seen in long term immobilized limbs. Other main disadvantages associated with prolonged immobilization and bed rest are cardiovascular effects, especially in the elderly, such as reduced plasma volume, increased venous compliance and reduced cardiac output. Despite the willingness to comply, patients often do not follow the restrictions in weight bearing and advance their weight bearing as fracture healing progresses. In the elderly population there is a higher incidence of postoperative delirium and a significant prevalence of cognitive impairment, leading to the question of how well this patient population can follow instructions, restricting their rehabilitation. In one study a postoperative compliance rate to a non- or partial weight bearing regimen of up to 37.5% was found. Moreover, most patients were not able to adhere to the loading limitation protocol, even a few days after surgery and even if the patients were trained by a physiotherapist, based upon cognitive impairments.¹¹

Moreover, according to a recent systematic review¹² only a few rehabilitation protocols aimed at surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities have been found in the literature, often lacking information about the exact therapeutic strategy and scientific evidence on which the content of described rehabilitation programmes were based. In view of this lack of evidence, many orthopaedic and trauma surgeons tend to advise conservatively in regards to weight bearing in rehabilitation, and hold on to the prevailing dogmas, i.e. recommending time-contingent progression of weight bearing, while physiotherapists and rehabilitation physicians had the tendency to follow a more progressive approach towards fracture weight bearing. Besides, even with specific advice from specialists, as previously mentioned patients may not always be committed to complying with non-weight bearing advice.^{13,14} Furthermore, the lack of individual feedback on the actual weight bearing status causes great differences in weight bearing when the patient is advised restricted weight bearing.¹⁴⁻¹⁶ These circumstances give rise to a wide range of weight bearing patterns and inconsistent aftercare treatment.^{17,18}

In the Netherlands we have found that even when choosing the time period of restricted weight bearing after surgically treated tibial plateau fractures, the vast majority of the responding orthopedic and trauma surgeons deviated from their own institutional guidelines and AO-guidelines, based on their own clinical experience and gut feeling and based on the prevailing currents trends. Although not all surgeons may be aware of these current guidelines, more likely, the surgeons act on their own clinical experience when choosing the aftercare trajectory.

A study by Thewlis et al.¹⁹ demonstrated that postoperative permissive weight bearing is safe, with no radiographic fracture reduction and migration in any patient after 52 weeks. Nevertheless, other key endpoints such as Activities of Daily Living and complications such as non-union, avascular necrosis, infection, but also quality of life outcomes and cost-effectiveness have not been comprehensively presented in the literature to our knowledge at the time of commencement of the individual studies reported in this thesis.

Therefore, the aim of this thesis was to further study the use and effectiveness of permissive weight bearing in comparison to the currently adopted restricted weight bearing regimens.²⁰ Our hypothesis was that the permissive weight bearing protocol is beneficial and has potential to be implemented in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities.²⁰

In our research we were able to present a permissive weight bearing aftercare protocol which could serve as a general reference framework and a starting point for discussion on the systematic optimization of allied health aftercare in surgically treated patients with fractures of the lower extremities, rather than as a library of predefined standard solutions ('cookbook'). In the studies that followed, all major 'International Classification of Functioning, Disability and Health' (ICF) domains have been addressed when comparing permissive weight bearing with restricted weight bearing.

Back to back with the publication of the permissive weight bearing aftercare protocol the first experience in 150 surgically treated trauma patients with peri- and/or intra-articular fractures of the pelvis and lower extremities with this aftercare protocol was presented in this thesis. This pilot study found that 52% of the patients with surgically stabilized (peri)- or intra-articular fractures using a PWB regime according to the in-house PROMETHEUS aftercare protocol were able to walk with full weight bearing within 12 weeks, indicating a mean shortening of 4 weeks compared to the current non-weight bearing guidelines. The total complication rate with permissive weight bearing was 10.0%, which were lower compared to current non-weight bearing guidelines.²¹

When comparing the PWB regime to a RWB regime in a smaller non-randomized cohort (N=91) in this thesis in terms of quality of life, time to full weight bearing, and number of complications in patients with surgically treated tibial plateau fractures, no differences were found in either patient-reported SF-12 (quality of life) or VAS scores (pain) between the PWB group and RWB group. Time to full weight bearing was significantly shorter in the PWB than in the RWB group, i.e., 14.7 versus 20.7 weeks, ($p=0.02$). No differences were found regarding postoperative complications between the PWB and the RWB groups, i.e., 6.5% versus 10.0%, respectively. Furthermore, no significant differences were found in rates of postoperative removal of osteosynthesis material or the need for total knee prostheses after tibial plateau fractures. In our study 28.3% of patients in the RWB were already bearing full weight within 12 weeks, highlighting the contrast to the standard protocol of 12 weeks non-weight bearing. The patients in the PWB group were already bearing full weight 6 weeks earlier than the RWB group. In addition, earlier studies reported that one third of the patients do not (fully) comply to a non- or restricted weight bearing regimen.^{15,17,22} A number of studies found patients to exceed the prescribed amount of partial weight bearing even when self-reported compliance was high.^{17,22}

In another prospective multicenter study in this thesis, the aim was to investigate the effectiveness of a PWB in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. This study included 106 trauma patients (N=53 in both the PWB and RWB groups). Significantly better ADL and QoL but no significant differences in postoperative complication rates were found for the PWB group compared to the RWB groups. In comparison in a larger literature study on 4918 elderly patients with a fracture of the hip²³ it was found that postoperative weight-bearing restrictions even led to a significantly greater risk of developing most adverse events compared with those who are encouraged to bear weight as tolerated. In another randomized literature study on 115 ankle fractures²⁴ unprotected weight-bearing and mobilization as tolerated as postoperative care regimen compared to restricted weight bearing regimens improved short-term functional outcomes similarly to our study and led to earlier return to work and sports. On the other hand it did not result in a significant increase of complications or reduction of quality of life scores.

Interestingly was the data from this thesis on weight bearing, as measured with the Moticon insoles. The measurements showed that there was no significant difference in mean weight bearing between the RWB and PWB groups. Point of discussion here is that even while instructions for rehabilitation given to patients may be clear, patient compliance with a non-weight bearing or limited weight bearing regime has been found to be poor.¹⁷ Several studies found that patients had actually exceeded the prescribed amount of partial weight bearing even though their self-reported compliance was high.^{17,22} For example, Braun et al used for their study a

continuously measuring pedobarography insole (Moticon) to measure the weight bearing in trauma patient with fractures of the lower extremities. The study showed that, despite physical therapy training, weight-bearing compliance to recommended limits was low and was apparently well tolerated.²⁵ That means that the aftercare could be accomplished in a more timely fashion within a safe way when using a permissive weight bearing protocol.

Finally in this thesis, in a prospective study, the cost-effectiveness in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities was estimated. In the Netherlands, annually, the incidence of peri- and/or intra-articular fractures of the lower extremities is more than 25,000 patients.²⁶ This study found that the PWB protocol is €457.51 cheaper compared to the usual current RWB protocol. Annually, this may result in a saving of at least €11,437,750 in the Netherlands. So, the permissive weight bearing protocol is more cost-effective and will contribute to a cheaper health care.

In our opinion, we, as surgeons, should be brave and start as a community to let the patients mobilize earlier according to their toleration level, as the future requires a holistic view of our patient population.

Overall conclusion

This thesis has shed more light on the efficacy and (cost)-effectiveness of a permissive weight bearing protocol in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. In light of the positive findings of PWB in comparison to RWB, it contests the paradigm behind the current guidelines, which have remained unchanged for well over 60 years. In line with our research objectives from chapter 2 we would like to summarize and conclude that:

1. To optimize recovery with a minimal complication rate, it is recommended to use a treatment intensity that is near to the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading, and that such treatment is guided by the permissive weight bearing protocol.
2. Consensus about the weight bearing aftercare for tibial plateau fractures is limited. A large majority of surgeons do not follow the AO guideline or their own local protocol. More transparent criteria and predictors are needed to design optimal weight-bearing regimes for the aftercare of tibial plateau fractures.
3. The economic burden in monetary terms and the effect on QoL of patients with peri- and/or intra-articular fractures of the lower extremities during the first 6 months follow-up has been presented.
4. The permissive weight bearing protocol is a patient-tailored and safe protocol. Given the low complication rate, the protocol may be beneficial to implement in

the treatment of trauma patients with surgically treated articular or peri- and/or intra-articular fractures of the pelvis and lower extremities.

5. Permissive weight bearing after surgically treated tibial plateau fractures is safe and is related to a significantly reduced time to full weight bearing with no significant differences in patient-reported quality of life and pain or complication rates.
6. In a prospective, comparative, multicenter study, we found that permissive weight bearing in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities is effective (less time to weight bearing) and is associated with a significant reduction in time to full weight bearing and significantly better outcomes in terms of ADL and quality of life compared to the restricted weight bearing regime, with comparable complication rates among both regimes.
7. Permissive weight bearing is more cost-effective compared to the restricted weight bearing regimen. Moreover, the permissive weight bearing group showed more improvement in ADL and quality of life compared to the restricted weight bearing group. Looking at the incremental economic analyses, permissive in comparison to restricted weight bearing was less expensive and yielded more effects in terms of ADL performance.

Future perspectives

Despite the addition of a substantial body of work in this thesis in the evidence based approach to aftercare protocols in patients with peri- and intra-articular fractures of the lower extremities, we believe important work still will need to be carried out in order to improve future PWB protocols.

Permissive weight bearing requires high-level evidence from randomized controlled-trials per individual type of peri- and intra-articular fracture of the lower extremities, as physiological differences in weight bearing might need to be taken into account in future PWB protocols.

Certainly the safety of PWB protocols in all patients needs to be addressed, for instance by taking into account negatively influencing clinical factors such as osteoporosis, diabetes mellitus, arthritis etc.

Furthermore, in this thesis, surgeon-oriented functional outcome scores (e.g. the function of a knee or ankle joint) were not taken into account, information which might improve awareness and agreement from the surgeon community with PWB aftercare protocols.

No radiological assessment was used to assess the alignment of the fractures during aftercare treatment and therefore no evidence on the amount of discordance between patient-reported outcomes and radiological alignment is available currently. The answer to this question might indicate whether more frequent/longer radiological follow-up is required in the current PWB aftercare protocols.

A long-term follow-up period might be needed to provide more evidence into functional outcome and complications (effectiveness) of PWB in comparison to RWB. In summary, future studies are needed on the long-term (cost)-effectiveness, radiological assessment, and long-term patient-reported outcomes of the PWB strategy in comparison to RWB.

Implementation of PWB-based treatment regimen in the rehabilitation community across the world is a challenge that needs to be addressed. This thesis showed that permissive weight bearing is safe, effective and cost-effective to be implemented in trauma patients with peri and or intra-articular fractures of the lower extremities. The patients should not longer be restricted in weight bearing. More insight in permissive weight bearing and more effort is needed to optimize the implementation of permissive weight bearing across the world. Implementation activities will be tailored to barriers and facilitators to change. We identified as most important barriers the necessary change in mindset in trauma- and orthopaedic surgeons who need to de-implement the current strategy of prolonged non-weight bearing and the lack of knowledge in physiotherapists. Implementation activities will focus on increasing awareness in trauma and orthopaedic surgeons. In trauma and orthopaedic surgery the international guidelines of the AO foundation are an important tool in implementing new practices. These guidelines are widely used in Europe and are translated in Dutch language for use at a national level. Adaptation of the AO fracture guideline is important for successful implementation of permissive weight bearing. Furthermore, educational activities have to be deployed to improve knowledge and skills of physiotherapists. These activities will be multimodal and comprise educational materials and large and small scale educational meetings. Finally, an application for mobile devices is needed to guide the permissive weight bearing at patient level.

References

1. Joeris A, Höglinger M, Meier F. et al. The impact of the AO Foundation on fracture care: An evaluation of 60 years AO Foundation. *Injury*. 2019;50:1868-75.
2. Ruedi TP, Buckley RE, Moran CG. AO principles of fracture management. Third edition. New York: Thieme. 2018.
3. Bailon-Plaza A, van der Meulen MC. Beneficial effects of moderate, early loading and adverse effects of delayed or excessive loading on bone healing. *J Biomech*. 2003;36:1069-77.
4. Gardner MJ, van der Meulen MC, Demetrakopoulos D et al. In vivo cyclic axial compression affects bone healing in the mouse tibia. *J Orthop Res*. 2006;24:1679-86.
5. Prendergast PJ, & Huiskes R. The Biomechanics of Wolff's law: Recent advances. *Ir J Med Sci*. 1995;164: 152-4.
6. Claes LE, Heigele CA, Neidlinger-Wilke C et al. Effects of mechanical factors on the fracture healing process. *Clin Orthop Relat Res*. 1998:S132-47.
7. Kenwright J, Gardner T. Mechanical influences on tibial fracture healing. *Clin Orthop Relat Res*. 1998;355(SUPPL.):S179-90.
8. Palke L, Schneider S, Karich B et al. Anti-gravity treadmill rehabilitation improves gait and muscle atrophy in patients with surgically treated ankle and tibial plateau fractures after one year: A randomised clinical trial. *Clin Rehabil*. 2022;36:87-98.
9. Potter B. From Bench to Bedside: Our Patients Want to Move, So Why Are We Slowing Them Down? *Clin Orthop Relat Res*. 2021;479:2369-70.
10. Trompeter A. A call to arms: It's time to bear weight! *Bone Joint J*. 2020;102:403-6.
11. Eickhoff AM, Cintean R, Fiedler C et al. Analysis of partial weight bearing after surgical treatment in patients with injuries of the lower extremity. *Arch Orthop Trauma Surg*. 2022;142: 77-81.
12. Schnackers MLAP, van Horn YY, Meys GHH, Brink PRG et al. Evidence-based rehabilitation therapy following surgery for (peri-)articular fractures: A systematic review. *J Rehabil Med*. 2019;51:638-45.
13. Gray FB, Gray C, McClanahan JW. Assessing the accuracy of partial weight-bearing instruction. *Am J Orthop (Belle Mead NJ)*. 1998;27:558-60.
14. Hurkmans HL, Bussmann JB, Selles RW et al. The difference between actual and prescribed weight bearing of total hip patients with a trochanteric osteotomy: long-term vertical force measurements inside and outside the hospital. *Arch Phys Med Rehabil*. 2007;88:200-6.
15. Hustedt JW, Blizzard DJ, Baumgaertner MR et al. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthopedics*. 2012;35:e31-7.
16. Westby MD, Backman CL. Patient and health professional views on rehabilitation practices and outcomes following total hip and knee arthroplasty for osteoarthritis: a focus group study. *BMC Health Serv Res*. 2010;10:119-33.
17. Westby MD, Brittain A, Backman CL. Expert consensus on best practices for post-acute rehabilitation after total hip and knee arthroplasty: a Canada and United States Delphi study. *Arthritis Care Res*. 2014;66:411-23.
18. de Boer AS, van Lieshout EMM, van Moolenbroek G et al. The effect of time to post-operative weightbearing on functional and clinical outcomes in adults with a displaced intra-articular calcaneal fracture; A systematic review and pooled analysis. *Injury*. 2018;49:743-52.
19. Thewlis D, Frayse F, Callary SA et al. Postoperative weight bearing and patient reported outcomes at one year following tibial plateau fractures. *Injury*. 2017;48:1650-6.
20. Kalmet PHS, Meys G, V Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg*. 2018;18:8.
21. Basques BA, Webb ML, Bohl DD et al. Adverse events, length of stay, and readmission after surgery for tibial plateau fractures. *J Orthop Trauma*. 2015;29:e121-6.
22. Warren CG, Lehmann JF. Training procedures and biofeedback methods to achieve controlled partial weight bearing: an assessment. *Arch Phys Med Rehabil*. 1976;56:449-55.
23. Ottesen TD, McLynn RP, Galivanche AR et al. Increased complications in geriatric patients with a fracture of the hip whose postoperative weight-bearing is restricted: An analysis of 4918 patients. *Bone Joint J* 2018;100:1377-80.

24. Smeeing DPJ, Houwert RM, Briet JP et al. Weight-bearing or non-weight-bearing after surgical treatment of ankle fractures: a multicenter randomized controlled trial. *Eur J Trauma Emerg Surg.* 2020;46(1): 121-30.
25. Braun BJ, Veith NT, Rollmann M et al. Weight-bearing recommendations after operative fracture treatment—fact or fiction? Gait results with and feasibility of a dynamic, continuous pedobarography insole. *Int Orthop* 2017;41(8):1507-12.
26. Landelijk netwerk acute zorg. [National network acute care] Landelijke traumaregistratie [National trauma registry] 2010-2014. The Netherlands. 2015. Available from: http://www.lnaz.nl/cms/LNAZ_LTR_rapportage_2010-2014.pdf.

Summary

This dissertation focuses on: 1) the current state of practice among surgeons in the Netherlands regarding post-treatment weight bearing protocols 2) the current economic burden regarding non- or restricted weight bearing 3) a comprehensive protocol for permissive weight bearing and 4) the (cost) effectiveness of permissive weight bearing versus non- or restricted weight bearing (current guidelines).

As mentioned in the introduction (**chapter 1**), the permissive weight bearing protocol has been conceptualized as a new aftercare mobilization regimen to optimize rapid clinical recovery and the restoration of function and functionality in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. Since 60 years, the current paradigm of aftercare treatment in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities has not changed, namely non- or restricted weight bearing during 6-12 weeks. However, studies substantiating the non- or restricted weight bearing protocol are lacking. In addition, studies comparing permissive weight bearing versus non- or restricted weight bearing are scarce. Therefore, more evidence is needed regarding the permissive weight bearing protocol.

In **chapter 3**, a web-based survey among members of the Dutch Trauma Society and Dutch Orthopaedic Society is presented, identifying the most commonly applied protocols in terms of the post-operative initiation and level of weight bearing in patients with tibial plateau fractures and the surgeons reasoning behind this choice. One hundred and eleven surgeons responded to the survey; 72.1% of the respondents recommended starting weight bearing earlier than the 12 weeks recommended by the AO guideline (current guideline); 11.7% recommended starting weight bearing immediately, 4.5% after 2 weeks and 55.9% after 6 weeks. Moreover, 88.7% of the respondents reported deviating from their own local protocol. There is little consensus about the definition of 100% weight bearing and how to build up weight bearing over time. This study demonstrates that consensus about the weight bearing aftercare for tibial plateau fractures is limited. A large majority of surgeons do not follow the AO guideline or their own local protocol.

In **chapter 4**, in a prospective cohort study, the cost of illness in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities was estimated through a bottom-up method. The Dutch EQ-5D-5L questionnaire was used to calculate utilities while Lower Extremity Functional Scale (LEFS) scores were used as a measure of Activities of Daily Living (ADL). Subgroup analyses were performed to determine the influence of work status. Furthermore sensitivity analyses were performed to test the robustness of the results. Total average societal costs were

€9,836.96 over six months. Unexpectedly, total societal and healthcare costs were lower for patients with a paid job relative to patients without a paid job. The ADL was, respectively 10.4 at baseline and 49.5 at 26 weeks post-surgery treatment. The Quality of life (QoL) at baseline was 0.3 and at 26 weeks post-surgery treatment it was 0.7. These findings are indicative of a significantly improved ADL and QoL ($p < 0.05$) over time.

In **chapter 5**, the newly designed permissive weight bearing protocol presented in chapter 1 was implemented in a patient population from Adelante Rehabilitation Center in Hoensbroek, the Netherlands. The protocol, designed as a new aftercare mobilization regimen within the upper boundary of the therapeutic bandwidth, yet safe enough to avoid overloading, has been further elaborated in this chapter. The first experience in 150 surgically treated trauma patients with peri- and/or intra-articular fractures of the pelvis and lower extremities has been investigated. The study showed that the median time to full weight bearing was 12.0 weeks [IQR 6.8, 19.2]. The complication rate during rehabilitation was 10%, which is comparable to the complications rates in the literature.

In **chapter 6**, quality of life and pain, and number of complications in patients with surgically treated tibial plateau fractures who followed a permissive weight bearing (PWB) regime, relative to those that followed a restricted weight bearing (RWB) regime were compared. This cohort study included 91 patients with a tibial plateau fracture (31 and 60 patients in the PWB and RWB groups respectively). No between-group differences in either age or gender were found. However, a significant difference in fracture type was found between groups, ($p = 0.04$). No differences were found in either patient-reported SF-12 (quality of life) or VAS scores (pain) between the PWB group and RWB group. Time to full weight bearing was significantly shorter in the PWB than in the RWB group, i.e., 14.7 versus 20.7 weeks, ($p = 0.02$). No differences were found regarding postoperative complications between the PWB and the RWB groups, i.e., 6.5% versus 10.0%, respectively.

In the study reported in **chapter 7**, the aim was to investigate the effectiveness of a PWB in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. This study reports on patients' self-perceived outcome levels regarding activities of daily living (ADL), quality of life (QoL), pain and weight bearing compliance, in comparison to restricted weight bearing (RWB), over a 26-week post-surgery follow-up period. This study included 106 trauma patients ($N = 53$ in both the PWB and RWB groups). Significantly better ADL and QoL were found in the PWB group compared to the RWB group. There were no differences in postoperative complication rates between the PWB and RWB groups.

In the study reported in **chapter 8**, the cost-effectiveness and the cost-utility of the PWB protocol was compared to the standard RWB protocol from both a societal and a hospital perspective. This prospective comparative cohort study included surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities followed by PWB or RWB. Costs, Activities of Daily Living (ADL) and quality of life were measured during 26 weeks (at baseline, 2, 6, 12 and 26 weeks post-surgery). Cost per quality adjusted life year (QALY) gained (cost-utility) and cost per ADL or Life Years (cost-effectiveness) were estimated. This study included 106 trauma patients (N=53 in both the PWB and the RWB-group). There were no group differences in baseline characteristics. Costs were lowest for the PWB group (€9,379.45 vs. €9,836.96) during 26 weeks post-surgery.

Samenvatting

In dit proefschrift behandelt en analyseert de auteur kritisch: 1) de huidige stand van zaken omtrent de voorkeur van chirurgen in Nederland wat betreft nabehandelingsprotocollen ten aanzien van beenbelasting 2) de economische lasten van de huidige niet-belasten nabehandelingsprotocollen, 3) een uitgebreid beschreven permissive weight bearing protocol (d.w.z. vroeg belasten protocol) en 4) de effectiviteit en kosteneffectiviteit van permissive weight bearing vergeleken met non-weight bearing (niet-belasten nabehandelingsprotocollen).

Zoals beschreven in de introductie (**hoofdstuk 1**) is het permissive weight bearing protocol ontworpen om als nieuwe nabehandelingsprotocol te dienen, teneinde de nabehandeling te optimaliseren en te versnellen in geopereerde traumapatiënten met fracturen rond of in het gewrichtsoppervlak (peri- en/of intra-articulaire fracturen) van de onderste extremiteiten. De huidige richtlijnen in geopereerde traumapatiënten met peri- en/of intra-articulaire fracturen van de onderste extremiteiten zijn sinds 60 jaar ongewijzigd, namelijk non- of restricted weight bearing (onbelast mobiliseren) gedurende 6-12 weken. Bij aanvang van dit proefschrift waren er weinig tot geen studies die de huidige non-weight bearing protocollen onderbouwen. Daarnaast waren er weinig tot geen wetenschappelijke studies die permissive weight bearing versus non- of restricted weight bearing vergelijken. Derhalve was er meer wetenschappelijk onderzoek nodig om de permissive weight bearing protocol te onderbouwen.

In **hoofdstuk 3**, werd een online vragenlijst uitgezet naar alle chirurgen van de Nederlandse Vereniging voor Traumachirurgie en Nederlandse Orthopedische Vereniging om te achterhalen wat de voorkeur en exacte motivatie van chirurgen was voor nabehandelingstraject in geopereerde traumapatiënten met tibiaplateaufracturen. Honderd en elf chirurgen hadden de vragenlijsten ingevuld, 72.1% van de chirurgen adviseerden de patiënt om eerder dan 12 weken te starten met belasten in tegenstelling tot de voorgeschreven huidige niet-belasten richtlijnen (AO-richtlijn); 11.7% adviseerde de patiënt zelfs om direct te starten met belasten na de operatie, 4.5% na 2 weken te starten met belasten en 55.9% 6 weken na de operatie te starten met belasten. Daarnaast weken 88.7% van de chirurgen af van hun eigen lokale ziekenhuis nabehandelingsprotocol. Er is geen consensus over de definitie van 100% belasten en hoe de met de belasting gedurende de tijd dient op te voeren. Deze studie heeft laten zien dat er geen consensus is over de nabehandeling van tibiaplateaufracturen. Een grote groep chirurgen volgt de huidige non-weight bearing richtlijn of hun eigen lokale richtlijn niet.

In **hoofdstuk 4** werd gekeken naar de kosten van geopereerde traumapatiënten met peri- en/of intra-articulaire fracturen van de onderste extremiteiten gedurende de

eerste 6 maanden na operatie. De Nederlandse EQ-5D-5L vragenlijst werd gebruikt om de scores op verschillende gezondheidsniveaus te berekenen en de Lower Extremity Functional Scale (LEFS) werd gebruikt om de Algemeen dagelijkse activiteiten (ADL) te onderzoeken. Ook werd er een subgroep analyse uitgevoerd om de invloed van betaald werken te analyseren. De totale kosten waren gemiddeld €9.836,96 per patiënt gedurende de eerste 6 maanden na de operatie. De totale maatschappelijke- en zorgkosten waren lager voor patiënten met een betaalde baan dan voor patiënten zonder een baan. Gevoeligheidsanalyses toonden aan dat de keuze voor een maatschappelijk perspectief en de EuroQol, als primaire meetinstrument voor de verschillende gezondheidsniveaus een significant effect hadden op de uitkomsten. De ADL score bij baseline was 10,4 en na 6 maanden na operatie 49,5 (maximale score is 80). De kwaliteit van leven (KvL) score was bij baseline; 0,3 en 6 maanden na operatie 0,7. Deze bevindingen zijn indicatief voor een significant verbeterde ADL en KvL ($p < 0,05$) in de loop van de tijd.

In **hoofdstuk 5** werd het in hoofdstuk 1 gepresenteerde permissive weight bearing protocol verder beschreven in een patiëntenpopulatie die behandeld werd in het revalidatiecentrum Adelante te Hoensbroek. Het protocol benut de therapeutische bandbreedte van het revalidatietraject optimaal en is in voldoende mate veilig om verschijnselen en complicaties van overbelasting te voorkomen bij traumapatiënten met peri- en/of intra-artculaire fracturen van de onderste extremiteiten. De eerste ervaringen in 150 geopereerde traumapatiënten met peri- en/of intra-artculaire fracturen van de onderste extremiteiten zijn in dit stuk uitgebreid beschreven. De studie liet zien dat de gemiddelde tijd tot volledig belasten 12 weken na operatie was [IQR 6,8, 19,2]. De complicatiecijfers tijdens de revalidatie bedroegen 10%, hetgeen vergelijkbaar was met de complicatiecijfers van de non-weight bearing richtlijnen uit de huidige literatuur.

In **hoofdstuk 6** werd gekeken naar de kwaliteit van leven, pijn en complicatiecijfers in geopereerde traumapatiënten met tibiaplateaufracturen, die volgens de principes van permissive weight bearing werden nabehandeld. Er werden 91 patiënten met geopereerde tibiaplateaufracturen geïnccludeerd, 31 patiënten die permissive weight bearing als nabehandeling hadden ontvangen en 60 patiënten die non-weight bearing als nabehandeling hadden ontvangen. Er werd geen verschil in leeftijd en geslacht gezien tussen de permissive weight bearing (PWB) groep en de non- or restricted weight bearing (RWB) groep. Echter was er wel een verschil in fractuurtype tussen de PWB/RWB groepen ($p = 0,04$). Er werd geen verschil in kwaliteit van leven en pijn gezien tussen de PWB en RWB groepen. De tijd tot 100% belasten was significant korter in de PWB groep vergeleken met de RWB groep, i.e. 14,7 versus 20,7 weeks, ($p = 0,02$). Geen significant verschil in postoperatieve complicaties werden gezien tussen de PWB en RWB groep, i.e. 6,5% versus 10,0%, respectievelijk. De studie

liet zien dat permissive weight bearing als nabehandeling veilig is in geopereerde traumapatiënten met tibiaplateaufracturen, met een significant verkorte tijd tot 100% belasten met daarbij geen significante verschillen in kwaliteit van leven, pijn en complicaties ten opzichte van geopereerde traumapatiënten met tibiaplateaufracturen die non-weight bearing als nabehandeling hadden ontvangen.

In **hoofdstuk 7** werd de effectiviteit van permissive weight bearing in geopereerde traumapatiënten met peri- en/of intra-artculaire fracturen van de onder extremiteiten onderzocht. In deze studie werd gekeken naar Algemene Dagelijkse Levensverrichtingen (ADL), kwaliteit van leven, pijn en naleving van belasten bij patiënten die permissive weight bearing (PWB) volgden versus restricted weight bearing (RWB), over een periode van 26 weken na operatie. Er werden 106 patiënten geïnccludeerd (N=53 in de PWB groep en N=53 in de RWB groep). De ADL en kwaliteit van leven waren significant beter in de PWB groep dan in de RWB groep. Er werd geen verschil gevonden in postoperatieve complicaties tussen de PWB en RWB groepen. Deze studie laat zien dat permissive weight bearing in geopereerde traumapatiënten met peri- en/of intra-artculaire fracturen van de onder extremiteiten veilig en effectief is.

In **hoofdstuk 8** werd de kosteneffectiviteit van permissive weight bearing versus non-weight bearing onderzocht. In deze prospectieve studie werden geopereerde traumapatiënten met peri- en/of intra-artculaire fracturen van de onderste extremiteiten geïnccludeerd. In deze studie werd gekeken naar de kosten, ADL en kwaliteit van leven gedurende 26 weken na operatie. Kosten per quality adjusted life year (QALY) en kosten per ADL werden onderzocht. Er werden 106 patiënten geïnccludeerd (N=53 in de PWB groep en N=53 in de RWB groep). Er werden geen verschillen gezien in baseline karakteristieken. De kosten in de PWB groep waren minder vergeleken met in de RWB groep (€9.379,45 vs. €9.836,96), gedurende 26 weken na operatie. Deze studie laat zien dat permissive weight bearing in geopereerde traumapatiënten met peri- en/of intra-artculaire fracturen van de onder extremiteiten kosteneffectief is.

Study impact

Main research goal

The main research goal of this thesis was the comprehensive assessment in terms of ADL, quality of life, pain, postoperative complications and costs of permissive weight bearing versus the current standard restricted weight bearing aftercare protocols in surgically treated trauma patient with peri- and/or intra-articular fractures of the lower extremities. Permissive weight bearing (PWB) is effective and cost-effective and can be used as a novel approach in the aftercare treatment in surgically treated trauma patient with peri- and/or intra-articular fractures of the lower extremities. The PWB regimen led to the patients being able to bear full weight on their affected leg much sooner, with improved Activities of Daily Living and quality of life, compared to those who followed the current restricted weight bearing (RWB) regimen. No significant differences between the two treatment regimens were found in either postoperative complication rates or pain levels. Furthermore, total costs were lower in the PWB group in comparison to the RWB group. In terms of cost per improvement in ADL (as measured with the Lower extremity functional scale) the PWB group showed higher effects and lower costs. Looking at the quality of life the PWB group had comparable QALYs to the RWB group while the costs were lower. Therefore, as stated earlier in this thesis, these results show that PWB can be seen as a promising aftercare treatment in surgically treated trauma patient with peri- and/or intra-articular fractures of the lower extremities. This means, the PWB contests the paradigm of the current RWB guidelines, which have remained unchanged for 60 years.

Social and economic relevance of this thesis

With tighter healthcare budgets and a shortage in hospital and rehabilitation center staff, the societal and economic relevance for an effective and cost-efficient aftercare protocol has become ever more pressing. In the Netherlands, annually, the incidence of peri- and/or intra-articular fractures of the lower extremities is more than 25,000 patients.¹ These patients often suffer from sequelae and need long-term rehabilitation. The current postoperative management in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities is either non-weight bearing or restricted (or partial) weight bearing.^{2,3} According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) Principles of Fracture Management, postoperative management of peri- and/or intra-articular fractures of the lower extremities consist of non-weight bearing for 6-12 weeks, followed by partial weight bearing with a 25% increase in weight every week.² Full weight bearing in this method will be reached per protocol after 10-16 weeks post-surgery, but in practice may take significantly more time.^{4,5} As described earlier in this thesis, the recommendations for the current

postoperative management in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities are still more or less the same as they were during the last 60 years, without any source of evidence being given for the advice of restricted weight bearing.² Therefore, this thesis has added quality evidence in support of the use of permissive weight bearing in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities.

The results described in this thesis showed that the patients in the PWB group were bearing full weight 9 weeks earlier than those in the RWB group. The effort to bear weight earlier was not at the expense of longer duration of outpatient physiotherapy. In fact, the RWB group required significantly longer outpatient physiotherapy than the PWB group, viz. 41 versus 25 hours, respectively. Furthermore, significantly more patients in the PWB group completed the rehabilitation within 26 weeks compared to the RWB group, viz. 65.2% versus 34.8%. This means that the patients returned to social life and work much sooner, underpinning the important social relevance of the findings from this thesis. Furthermore, as described in chapter 8, PWB is accompanied by less costs over a period of 26 weeks post-surgery. The total costs per patient, consisting of patient-family expenses, healthcare costs and productivity loss, were €457.51 less in the PWB group. Annually this may result in a total saving of at least €11,437,750 in the Netherlands, a number of considerable economic relevance.

Target groups

The results in this thesis are promising regarding a novel approach involving permissive weight bearing (PWB) in all fit surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities. As there is at this point sufficient evidence that PWB is in comparison to RWB sufficiently both effective in terms of functional/health-related outcomes and cost-effective, we are advocating that all surgically treated trauma patient with peri- and intra-articular fractures of the lower extremities may be treated with the PWB protocol. The current, non- or restricted weight bearing guidelines should in our opinion be replaced by PWB protocols. To reach out the implementation of the PWB protocol, the surgeons should endorse the PWB protocol. With this thesis, we hope to change the mindset of both orthopedic and trauma surgeons to use the PWB protocol. Furthermore, the physical therapist has to be facilitated in carrying out the PWB protocol as described in chapter 5 by 1) Creating easily understandable therapeutic flow charts for treatment of patients with the PWB protocol 2) Educating junior physical therapists early on in their training in PWB .

Activities and products

The work in this thesis may result in various activities and products. First and foremost, it will result in the increase of accredited educational activities, both webinars and

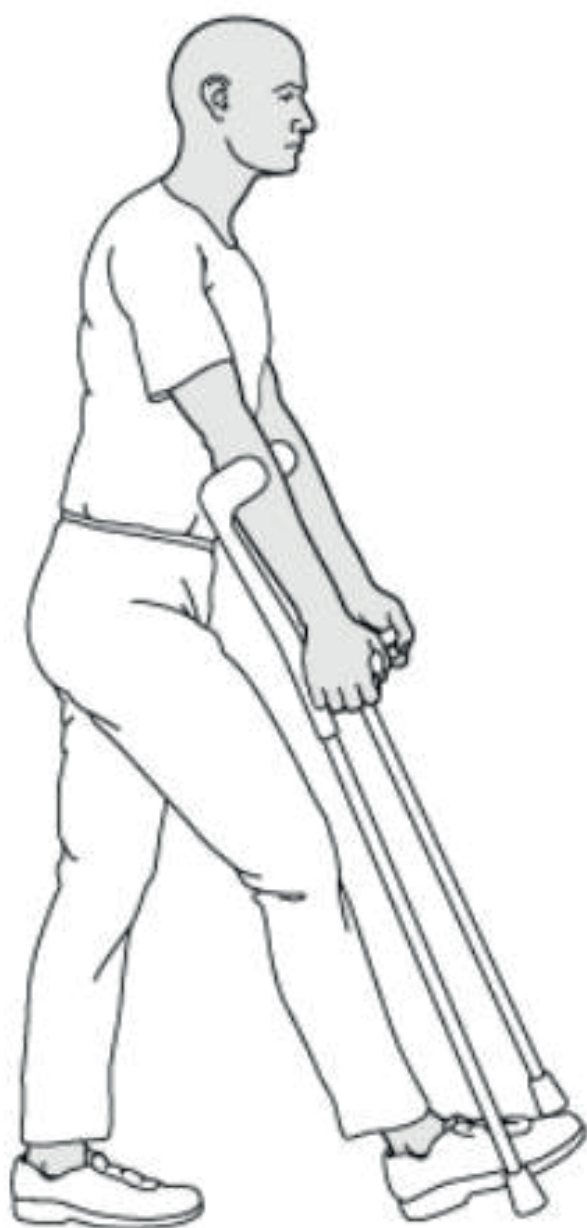
seminars as well as chapters in profession books for both orthopedic, trauma surgeons as well as physiotherapists and rehabilitation physicians regarding this topic. Products such as the pressure-measuring insoles can help guide the physical therapists with implementing future permissive weight bearing protocols.

Innovation

The main innovation of this thesis was that through investigation of various aspects of aftercare, from complications, pain to quality of life and economic burden of PWB versus RWB we have achieved for the first time a clear evidence based indication that PWB aftercare protocols are superior to RWB protocols. Implementation of PWB-based treatment regimen in the rehabilitation community across the world is a challenge that needs to be addressed.

References

1. Landelijk netwerk acute zorg. [National network acute care] Landelijke traumaregistratie [National trauma registry] 2010-2014. The Netherlands. 2015. Retrieved from: http://www.lnaz.nl/cms/LNAZ_LTR_rapportage_2010-2014.pdf.
2. Ruedi TP, Buckley RE, Moran CG. AO principles of fracture management. Third edition. New York: Thieme. 2018.
3. Haller JM, Potter MQ, Kubiak EN. Weight bearing after a periarticular fracture: what is the evidence? *Orthop Clin N Am*. 2013;44:509–19.
4. Meys G, Kalmet PHS, Sanduleanu S et al. A protocol for permissive weight-bearing during allied health therapy in surgically treated fractures of the pelvis and lower extremities. *J Rehabil Med*. 2019;51:290-7.
5. Kalmet PHS, Van Horn YY, Sanduleanu S et al. Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study. *Arch Orthop Trauma Surg*. 2019;139:483-8.



Appendix

Dankwoord

List of publications

Curriculum vitae auctoris

Dankwoord

Dit proefschrift was er niet gekomen zonder hulp. Ik wil dit dankwoord dan ook gebruiken om iedereen te bedanken die een bijdrage heeft geleverd aan het realiseren van dit proefschrift. In het bijzonder wil ik onderstaande mensen bedanken.

Prof. dr. P. Brink, beste Peter, beste promotor, bedankt voor de kans die u mij gegeven hebt om te starten met wetenschappelijk onderzoek. De tijd van wetenschappelijk onderzoek begon allemaal in 2012. Ik werd toen door u geopereerd aan mijn sleutelbeen. U kwam, na afloop van de operatie, mij bezoeken op de afdeling. Toen vroeg ik u om werk, in dezen wetenschappelijk onderzoek. U vertelde mij eerst rust te nemen en de eerstvolgende poliklinische afspraak daarop terug te komen. Ik mocht van u onderzoek doen bij mensen met een heupfractuur. Hierop volgend kon ik mijn wetenschappelijk stage over permissive weight bearing doen bij u. Direct na mijn geneeskunde opleiding gaf u mij de kans om aan het “slimme sok” project te werken en ook mijn promotieonderzoek betreffende permissive weight bearing te continueren. U gaf al in het begin aan dat u financiering had voor 1,5 jaar. In de tussentijd moesten wij een subsidie binnen halen, zodat ik verder kon met mijn promotie. Dit lukte ons ook, de aanvraag werd gehonoreerd en wij konden 2 jaar onderzoek doen naar permissive weight bearing in traumapatiënten met breuken van de onderste ledematen.

Dit allemaal heeft geleid tot verschillende publicaties en deze promotie. Ik dank u zeer voor uw vertrouwen en niet-aflatende steun in de afgelopen jaren. Ik heb veel van u kunnen leren.

Prof. dr. M. Poeze, beste Martijn, beste promotor, bedankt voor alles. Na het pensioen van Prof. Brink gingen we samen verder met het onderzoek. Ook mede dankzij jou hebben we de zonMW Open Doelmatigheid subsidie binnen kunnen halen. Naast mijn eigen promotieonderzoek, gaf jij mij de gelegenheid om mezelf verder te ontwikkelen. Van jou mocht ik studenten begeleiden met andere onderzoeken. Ik kon op ieder moment bij jou langs met vragen en opmerkingen over mijn proefschrift en dankzij jouw inzet en ondersteuning heb ik in die periode veel van mijn stukken kunnen afschrijven en publiceren. Ik hoop dat we samen nog veel meer kunnen publiceren. Bedankt voor alle mogelijkheden die je me hebt gegeven.

Dr. H. Seelen, beste Henk, beste copromotor, bedankt voor alle ondersteuning in de afgelopen jaren. Jij hebt mij geleerd hoe ik een subsidieaanvraag moet schrijven. Door jouw kritische blik en ervaring heb je mij tot een betere niveau getild qua artikelen schrijven. Ik vond de samenwerking met jou heel prettig. Hopelijk kunnen we deze manier van werken in de toekomst continueren.

Beste Yvette, Guido, Geert-Jan, Marielle, bedankt voor jullie tijd en inzet die jullie in mij hebben gestoken. Permissive weight bearing is allemaal begonnen in Adelante revalidatie centrum op de afdeling ATO. Het permissive weight bearing werd al jarenlang uitgevoerd bij jullie op de afdeling. Ik mocht een retrospectief onderzoek starten om te kijken of hetgeen jullie uitvoerden ook daadwerkelijk veilig was. Dat was het geval. Daarop volgde snel een permissive weight bearing protocol dat ik samen met jullie heb mogen publiceren. Bedankt voor de fijne samenwerking. Hopelijk kunnen we dit zo vast blijven houden in ons onderzoeksteam (PROMETHEUS).

Beste leden van de PROMETHEUS groep, dank voor jullie waardevolle adviezen en bijdragen aan dit boekje.

Beste Paul Hustinx en Raoul v. Vught (Zuyderland Medisch Centrum), bedankt voor jullie inzet en bijdrage aan dit boekje. We hadden laagdrempelig contact, waardoor de patiënten sneller geïncludeerd konden worden.

Beste Alexander vd Veen (Catharina ziekenhuis), Coen Jaspars (Maxima Medisch Centrum), Jan Bernard Sintenie (Elkerliek ziekenhuis), Heinrich Janzing (Viecuri Medisch Centrum), ook jullie bedankt voor jullie inzet en bijdragen aan dit boekje. Zonder jullie hadden we nu geen patiënten voor de controle-groep.

Leden van de beoordelingscommissie, geachte Prof dr. Verbunt, Prof dr. Geertzen, Prof dr. Edwards, Prof. dr. Lenssen en dr. Ten Bosch, bedankt voor het beoordelen van mijn proefschrift en de goedkeuring van mijn promotie.

Dank ook aan de revalidatieartsen van Adelante (Bea Hemmen, Martijn Dremmen, Peter Muijtens) die het gemakkelijk hebben gemaakt om de nazorg van de patiënten in de interventiegroep te regelen.

Beste Cherelle, Joey, Maartje, Eline en Janna, dank voor jullie waardevolle hulp en input aan het prospectieve onderzoek. Dankzij jullie hebben we alle metingen op verschillende meetmomenten zonder enige problemen kunnen doen.

Beste collega's van NAZL, dank voor alle ondersteuning! Ik vond het fijn om bij jullie op kantoor te kunnen zitten. Het werken met jullie in een team en ook de teamuitjes waren altijd een groot feest. Jullie bijdrage is belangrijk geweest voor dit proefschrift, waarvoor dank.

Beste Prof. Dr. S. Evers, bedankt voor jouw expertise (kosteneffectiviteit) en jouw bijdrage die je hebt geleverd voor dit proefschrift. Verder wil ik Max Andriessen en

Caecile Oyen ook bedanken voor het analyseren van de data en het meeschrijven aan de artikelen over de kosteneffectiviteit.

Alle co-auteurs, dank voor jullie waardevolle hulp en input voor de verschillende hoofdstukken.

Traumachirurgen en orthopeden van alle deelneemede centra, bedankt voor alle operaties bij traumapatiënten met fractures van de onderste extremiteiten.

Dank ook aan alle patiënten die hebben meegedaan aan de verschillende onderzoeken. Zonder hun waren er ook geen data en zonder data zou dit proefschrift nooit tot stand zijn kunnen komen.

Paranimfen, beste Sebastian en Cherelle, wat ben ik blij dat jullie mij bij willen staan als paranimfen tijdens de verdediging van mijn promotie.

Beste vrienden, het is altijd leuk om met jullie af te spreken. Hoewel we allemaal een drukke agenda hebben en elkaar niet iedere week zien. Nu het proefschrift af is, is er meer tijd voor nieuwe avonturen.

Beste familie en vrienden, bedankt voor jullie steun tijdens mijn promotietraject.

Beste Daja (mama) en Bawa (papa), bedankt voor al jullie steun. Jullie hebben mij altijd gemotiveerd het beste uit mezelf te halen. Daarnaast heb ik van jullie geleerd dat je met hard werken en je best doen heel ver kunt komen. Jullie zullen net zo trots zijn als ik, nu mijn proefschrift af is.

Mezelf kennende ben ik ongetwijfeld mensen vergeten te noemen; weet dat ik jullie extra dankbaar ben voor alles!

List of publications

1. **Kalmet PHS**, Koc BB, Hemmes B et al. Effectiveness of a Multidisciplinary Clinical Pathway for Elderly Patients With Hip Fracture: A Multicenter Comparative Cohort Study. *Geriatr Orthop Surg Rehabil.* 2016;7:81-5
2. **Kalmet PHS**, Sanduleanu S v. Horn Y et al. Is early Weight Bearing Allowed in Surgically Treated Talar Neck Fractures? *J Orthop Case Rep.* 2016;6:73-4
3. van der Vusse M, **Kalmet PHS**, Bastiaenen CHG et al. Is the AO guideline for postoperative treatment of tibial plateau fractures still decisive? A survey among orthopaedic surgeons and trauma surgeons in the Netherlands. *Arch Orthop Trauma Surg.* 2017;137:1071-5
4. **Kalmet PHS**, Meys G, v. Horn YY et al. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. *BMC Surg.* 2018;18:8
5. **Kalmet PHS**, Van Horn YY, Sanduleanu S et al. Patient-reported quality of life and pain after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study. *Arch Orthop Trauma Surg.* 2019;139:483-8
6. Meys G, **Kalmet PHS**, v. Horn Y et al. A protocol for permissive weight-bearing during allied health therapy in surgically treated fractures of the pelvis and lower extremities. *J Rehabil Med.* 2019;51:290-7.
7. **Kalmet PHS**, de Joode SGCJ, Fiddleleers AAA et al Long-term Patient-reported Quality of Life and Pain After a Multidisciplinary Clinical Pathway for Elderly Patients With Hip Fracture: A Retrospective Comparative Cohort Study. *Geriatr Orthop Surg Rehabil.* 2019;10:2151459319841743
8. de Joode SGCJ, **Kalmet PHS**, Fiddleleers AAA et al. Long-term functional outcome after a low-energy hip fracture in elderly patients. *J Orthop Traumatol.* 2019;20:20.
9. **Kalmet PHS**, Sanduleanu S. Primakov S et al. Deep learning in fracture detection; a narrative review. *Acta Orthop.* 2020;91:215-20.
10. Jagtenberg EM, **Kalmet PHS**, de Krom MAP et al. Feasibility and validity of ambulant biofeedback devices to improve weight-bearing compliance in trauma patients with lower extremity fractures: A narrative review. *J Rehabil Med.* 2020;31;52.
11. de Krom MAP, **Kalmet PHS**, Jagtenberg EM et al. Medium-term patient-reported Quality of Life and Activities of Daily Living in surgically treated trauma patients with pelvic, acetabular or combined pelvic and acetabular fractures in a retrospective single center study. *J Orthop Trauma.* 2021;35:192-7.
12. Jagtenberg EM, **Kalmet PHS**, de Krom MAP et al. Effectiveness of surgical treatments on healing of cartilage and function level in patients with osteochondral lesions of the tibial plafond: A systematic review. *Review J Orthop.* 2021;27:34-40.

13. de Krom MAP, **Kalmet PHS**, Jagtenberg EM et al. Diagnostic tools to evaluate ankle instability caused by a deltoid ligament rupture in patients with supination-external rotation ankle fractures: A systematic review and meta-analysis. *Injury*. 2021;S0020-1383(21)00808-1.
14. **Kalmet PHS**, Andriessen MT, Maduro CV et al. The economic burden of the postoperative management in surgically treated trauma patients with peri- and/or intra-articular fractures of the lower extremities: A prospective multicenter cohort study. *Injury*. 2021;S0020-1383(21)00920-7.
15. van den Boom NAC, van den Hurk AA, **Kalmet PHS** et al. Economic evaluations in fracture research An Introduction with examples of foot fractures. *Injury*. <https://doi.org/10.1016/j.injury.2022.01.013>.

Boekhoofdstuk

Meys G, **Kalmet PHS**, Poeze M, Seelen HAM. Permissive weight bearing in lower extremity fractures. *Acute Medical Rehabilitation* volume 2. 2019. (Accepted for publication).

Presentaties

Voordrachten op uitnodiging

1. Kalmet PHS. Permissive weight bearing in trauma patients with fractures of the lower extremities. Congresso Nazionale AIP, Brescia, Italië, 2021
2. Kalmet PHS. Permissive weight bearing in trauma patients with fractures of the lower extremities. Stichting AMI, Leiderdorp, Nederland, 2021
3. Poeze M, Kalmet PHS. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. Key note lecture. Traumadagen 2019. Amsterdam.
4. Kalmet PHS. Permissive weight bearing. Refereeravond revalidatiecentrum Blixembosch, Eindhoven, 2018.
5. Kalmet PHS. Permissive weight bearing in trauma patients with fractures of the lower extremities. Congresso Nazionale SIOT, Bari, Italië, 2018.
6. Kalmet PHS. Permissive weight bearing protocol. Limburgs Traumachirurgisch Genootschap (Limburgs traumatologisch genootschap), Herten, maart 2018.
7. Kalmet PHS. Fysiologische effecten van vroeg belasten na trauma. Afdeling orthopedie, MUMC, februari 2018.
8. Kalmet PHS. Vroege belasting bij traumapatiënten met fracturen van de onderste extremiteiten. Revalidatie centrum in Apeldoorn, oktober 2016.

Voordrachten

1. Kalmet PHS. Permissive weight bearing in trauma patients with tibial plateau fracture: prospective multicenter comparative cohort study. Traumadagen 2019. Amsterdam.
2. Kalmet PHS. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. VRA dagen 2019. Utrecht.
3. de Joode S, Kalmet PHS, Poeze M, Blokhuis TJ. Long-term functional outcome after a low-energy hip fracture in elderly patients. European Orthopaedic Research Society, 2019. Maastricht.
4. Kalmet PHS. Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study. Symposium 'Doelmatig van Start', 2018. Adelante revalidatie centrum, Hoensbroek. (1ste prijs beste presentatie).
5. Kalmet PHS. Vroege belasten bij traumapatiënten met fracturen van de onderste extremiteiten. Symposium Bijzonder BIJZONDER 2017, Adelante Hoensbroek. (**1ste prijs beste presentatie**).
6. Brink PRG, Kalmet PHS, v. Horn YY et al. Non-weight bearing: Where is the evidence? DKOU (Deutsche Kongress für Orthopädie und Unfallchirurgie) 2016, Berlijn.
7. Kalmet PHS. Vroege belasting bij traumapatiënten met fracturen van de onderste extremiteiten. Nationale traumadagen 2015, Amsterdam.
8. Kalmet PHS. Early weight bearing in trauma patients with fractures of the lower extremiteit. VRA dagen 2015, Rotterdam

Posters

1. Kalmet PHS et al. Effectiveness of permissive weight bearing in surgically treated trauma patients with peri- or intra-articular fractures of the lower extremities: a prospective comparative multicenter cohort study. Traumadagen 2019, Amsterdam.
2. Kalmet PHS et al. Compliance of weight bearing recommendations in surgically treated trauma patients with peri- and intra-articular fractures of the lower extremities: prospective comparative multicenter longitudinal cohort study. Traumadagen 2019, Amsterdam.
3. Kalmet PHS et al. Complications after permissive weight bearing in surgically treated trauma patients with pelvic & acetabular fractures: a retrospective cohort study. ECTES 2019, Praag, Tsjechië.
4. Kalmet PHS et al. Functional outcome after permissive weight bearing in surgically treated trauma patients with tibial plateau fractures: a retrospective cohort study. OTA 2018, Orlando the USA.

5. Guido Meys, Kalmet PHS, Sanduleanu S et al. A rehabilitation protocol for permissive weight bearing in surgically treated fractures of the lower extremities. 9th Symposium Zuyderland 2018, Sittard.
6. Kalmet PHS, v. Horn YY, Sanduleanu S et al. Functionele uitkomsten na vroege belasting bij traumapatiënten met geopereerde tibiaplateafracturen. Nationale traumadagen 2017, Amsterdam.
7. Kalmet PHS, Sanduleanu S, v. Horn YY et al. Case report: Is vroege belasting van een operatief behandelde talushalsfractuur toegestaan? Nationale traumadagen 2015, Amsterdam.
8. vd Vusse M, Kalmet PHS, Bastiaenen-Heuts CHG et al. Is de AO-richtlijn voor postoperatieve behandeling van tibiaplateafracturen nog wel maatgevend? De uitkomsten van de Tifrab (Tibiaplateafractuurbelasting) enquête. Nationale traumadagen 2015, Amsterdam. **(Prijs mooiste poster).**
9. Kalmet PHS, Koc BB, Hemmes B et al. Effectiviteit collum care protocol: een retrospectief multicenter onderzoek. Wetenschappelijk symposium 2015, Sittard
10. Kalmet PHS, Koc BB, Hemmes B et al. Effectiviteit collum care protocol: een retrospectief multicenter onderzoek. Nationale traumadagen 2014, Amsterdam.

Curriculum Vitae Auctoris

Pishtiwan Kalmet was born in Baghdad, Iraq, on December 25, 1987. In 1996, his parents with the entire family were forced to leave Iraq. Thereafter, they arrived in the Netherlands as refugees.

He graduated from high school in 2009 (VWO, Augustinianum, te Eindhoven). He studied medicine at the University of Maastricht and obtained his medical degree in 2016. During his last year he started with his scientific research under supervision of Prof. Dr. Peter Brink and Prof. Dr. Martijn Poeze at the Maastricht University Medical Center+ (MUMC+).



In January 2016, he started his PhD at the traumatology department at MUMC+. In July 2017, he applied for a ZONMW grant (open doelmatigheidssubsidie ZONMW 2018) on permissive weight bearing in surgically treated trauma patients with fractures of the lower extremities. The grant was honored and with the use of this grant he could start investigating the (cost-) effectiveness of permissive weight bearing in surgically treated trauma patients with fractures of the lower extremities. During 2016-2019, he continued his scientific research on permissive weight bearing, which led to his first publication in 2016 and finally to this thesis; Permissive weight bearing in trauma patients with peri- and intra-articular fractures of the lower extremities.

This thesis will be the basis for another two up-coming theses. Pishtiwan will help the two PhD-students to continue with scientific research regarding permissive weight bearing. He will help PhD-students and will be two times co-promotor.

In January 2022, he started his clinical career as an orthopedic specialist in trainee.

Curriculum Vitae Auctoris

Pishtiwan Kalmet werd geboren in Bagdad te Irak op 25 december 1987. In 1996 waren zijn ouders gedwongen om met de hele gezin Irak te verlaten. In dat jaar vroegen ze asiel aan in Nederland. Pishtiwan behaalde zijn VWO diploma in 2009 op het Augustinianum te Eindhoven. Hij studeerde geneeskunde aan de Universiteit van Maastricht en behaalde zijn master diploma in 2016. Gedurende zijn laatste jaar startte hij met wetenschappelijk onderzoek onder supervisie van Prof. Dr. Peter Brink en Prof. Dr. Martijn Poeze in het Maastrichts Universitair Medisch Centrum+ (MUMC+).

In januari 2016, begon hij aan zijn promotie op de traumatologie afdeling in het MUMC+. In 2017 diende hij een ZONMW subsidie in (open doelmatigheidssubsidie ZONMW 2018). De subsidie werd dat jaar gehonoreerd en daarmee kon hij de (kosten-) effectiviteit van permissive weight bearing in geopereerde traumapatiënten met fracturen van de onderste extremiteiten onderzoeken. Gedurende de jaren 2016-2019 continueerde hij zijn wetenschappelijk onderzoek naar permissive weight bearing, dat leidde tot zijn eerste publicatie in 2016 en tot zijn proefschrift: Permissive weight bearing in trauma patients with peri- and intra-articular fractures of the lower extremities.

Dit proefschrift is de basis voor nog 2 andere aankomende proefschriften. Pishtiwan zal de twee PhD-studenten helpen om het verdere onderzoek over permissive weight bearing te vervolgen, zo ook om 2x co-promotor te worden.

In januari 2022 is Pishtiwan gestart als arts-assistent in opleiding tot specialist orthopedie.

